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Rosenberg

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[54] DOUBLE CHAMBER TISSUE EXPANDER

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[51] Int. Cl.[6] A61F 2/12

[52] U.S. Cl. 623/8; 604/890.1; 604/891.1; 604/101

[58] Field of Search 623/8; 604/890.1, 604/891.1, 101; 606/191, 192; 600/31

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Attorney, Agent, or Firm—Klauber & Jackson

[57] ABSTRACT

A tissue expansion device for subcutaneous implantation in a patient consisting of an implantable expandable bladder prepared from a porous material which defines an infusion solution chamber, and an inner bladder disposed within the outer bladder prepared from an expandable non-porous material which defines an expansion solution chamber. Liquid transport means are provided for introducing and removing an infusion solution into and out of the infusion solution chamber, and fluid transport means are provided for introducing and removing an expansion fluid into and out of the expansion solution chamber. Following implantation of the tissue expansion device subcutaneously, expansion fluid can be introduced into the expansion chamber by use of the fluid transport means causing the inner bladder to expand. The expansion of the inner bladder exerts pressure on the infusion chamber, which contains infusion solution introduced through the liquid transport means. The infusion solution passes through the pores of the expandable porous material into the tissue surrounding and contacting the expansile porous wall of the implanted tissue expansion device. The outer bladder also expands, due primarily to expansion of the inner bladder and to introduction of infusion solution. The infusion solution can contain agents to facilitate the expansion process, such as hyaluronidase, lidocaine, epidermal growth factor, or dexamethasone, or any combination thereof.

14 Claims, 5 Drawing Sheets

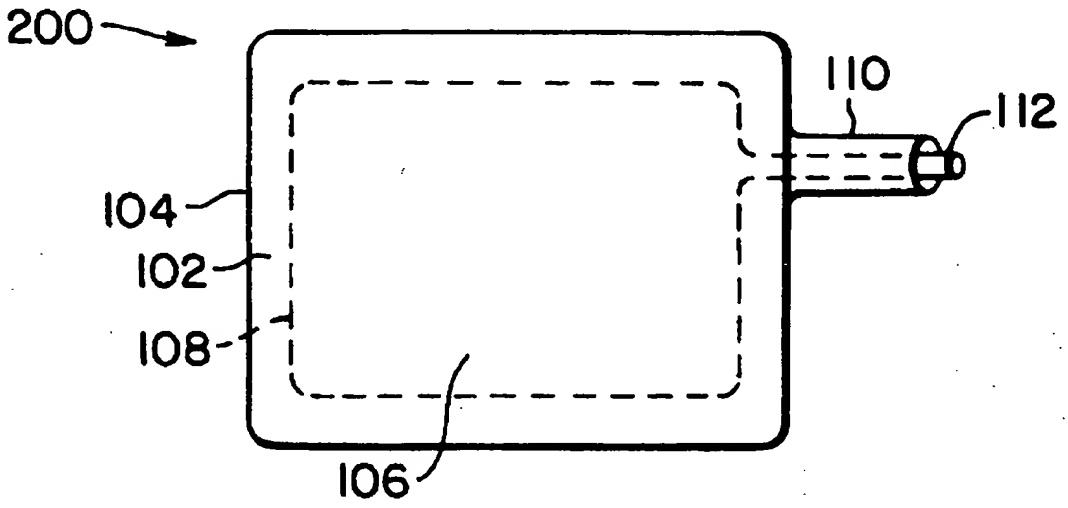


FIG. 1A

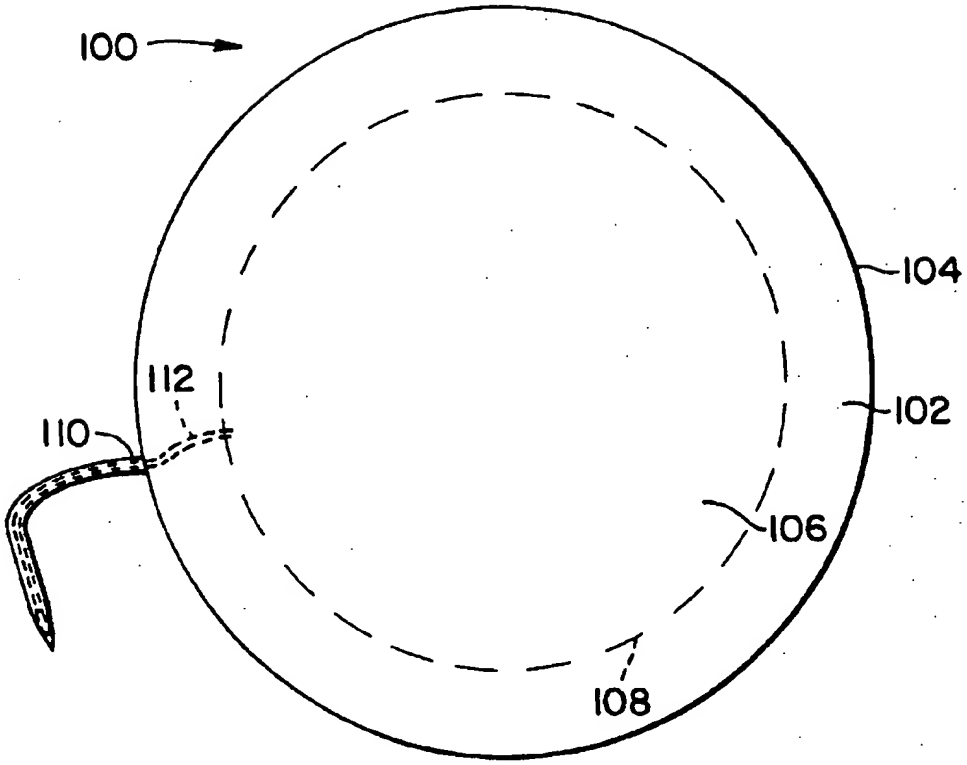


FIG. 1B

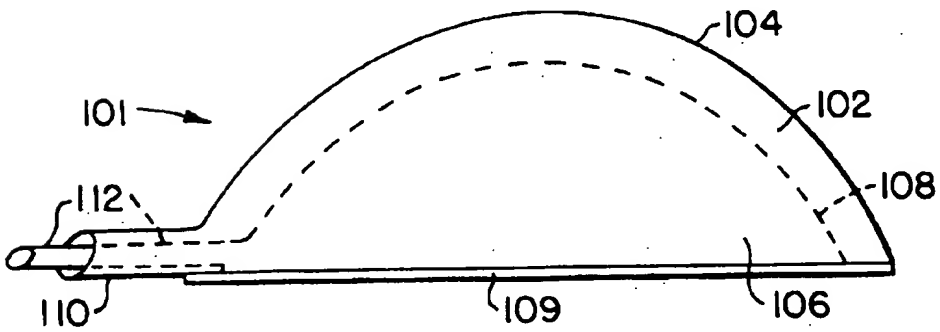


FIG. 2

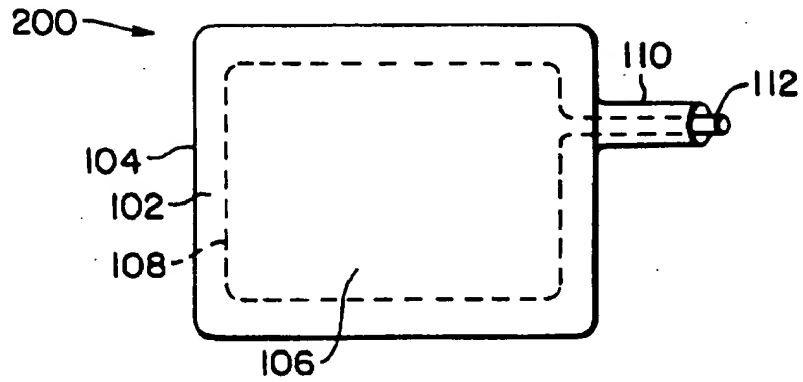


FIG. 3

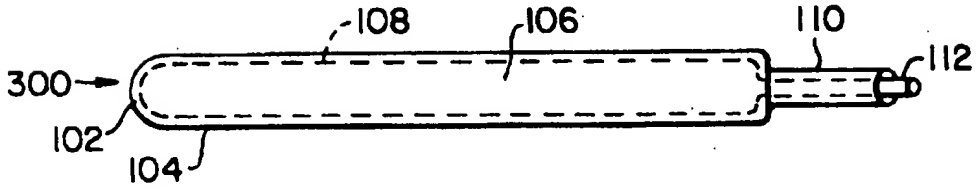


FIG. 4

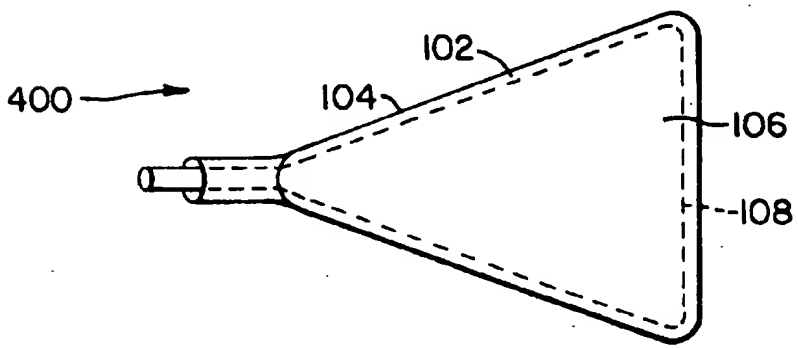


FIG. 5A

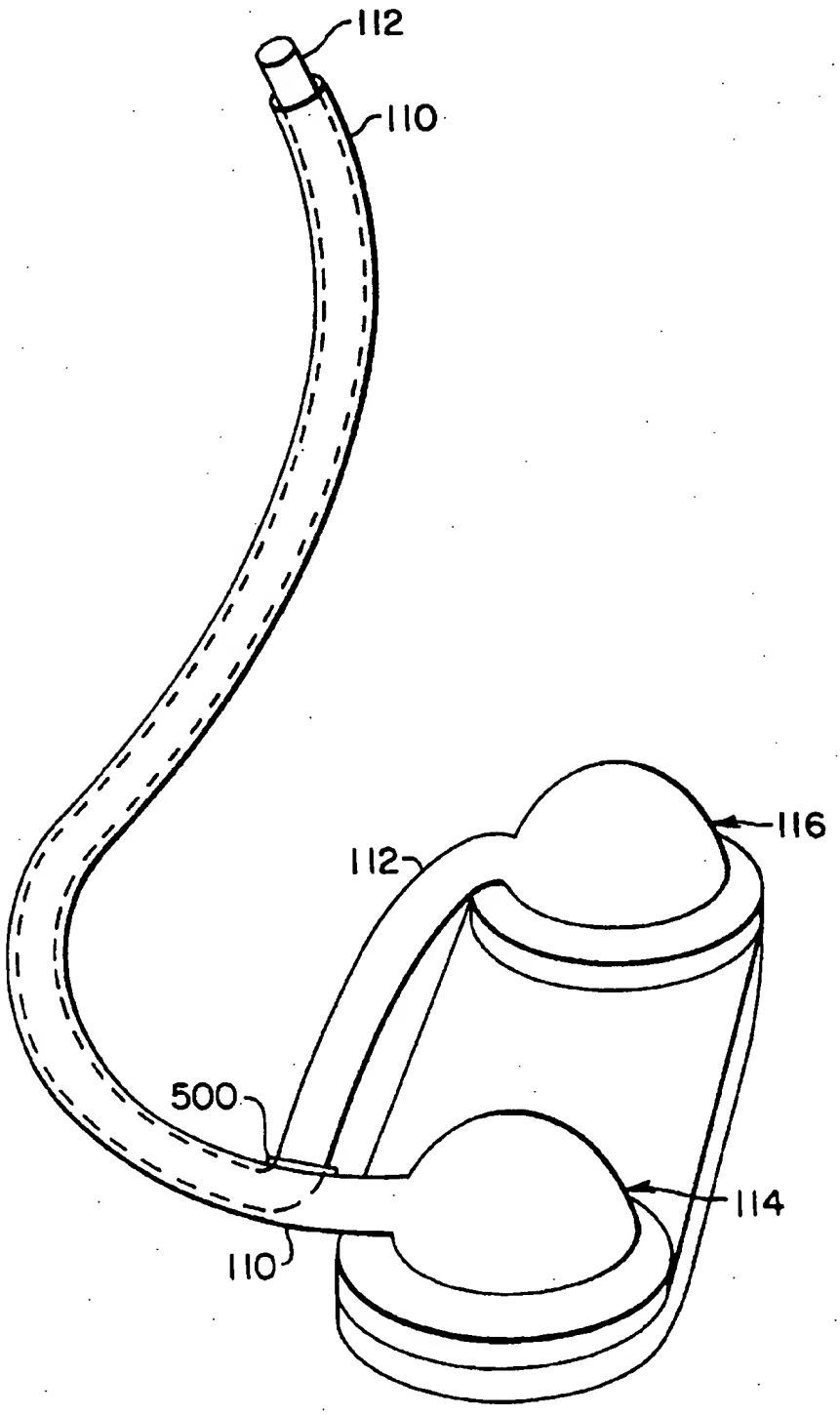


FIG. 5B

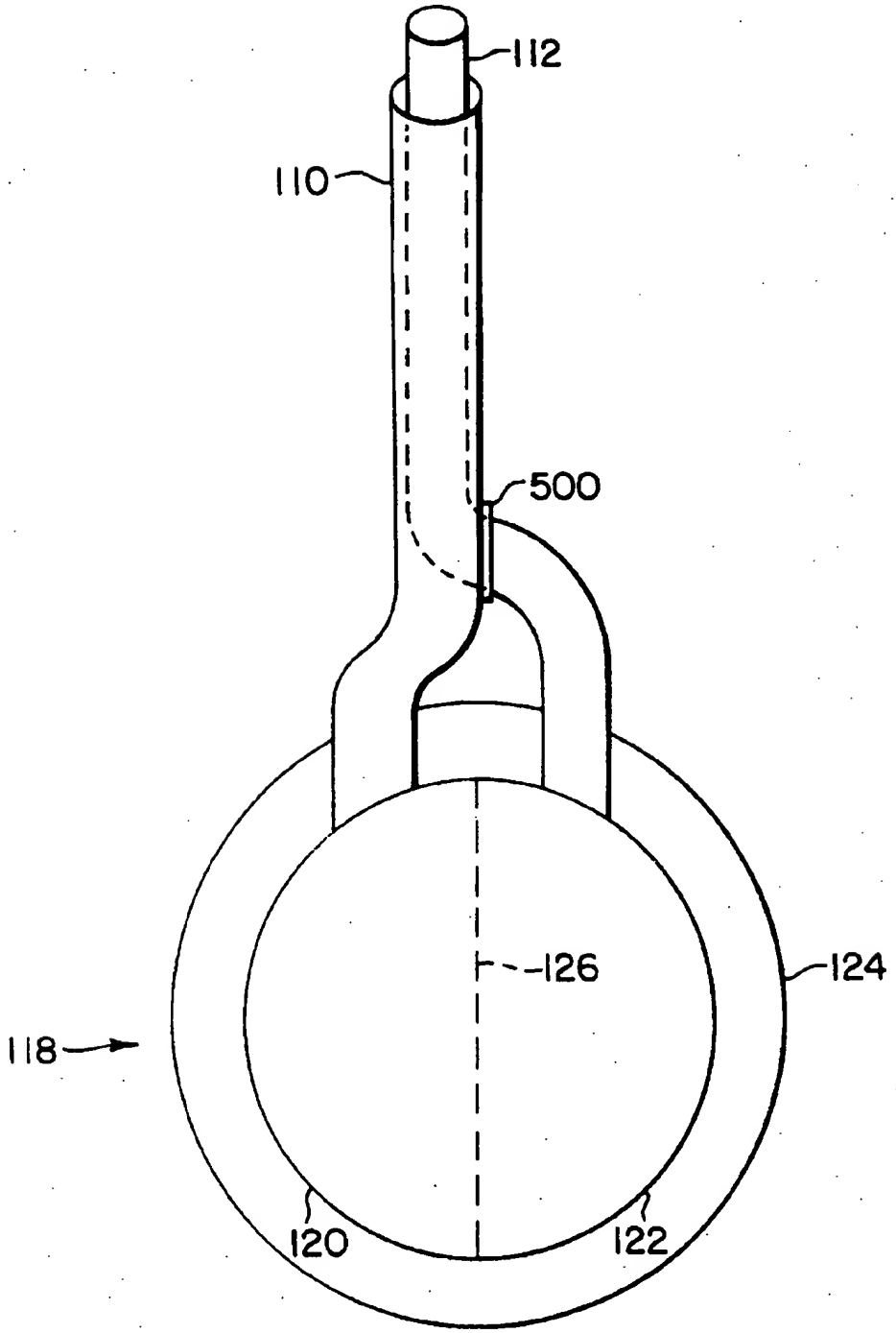


FIG. 6A

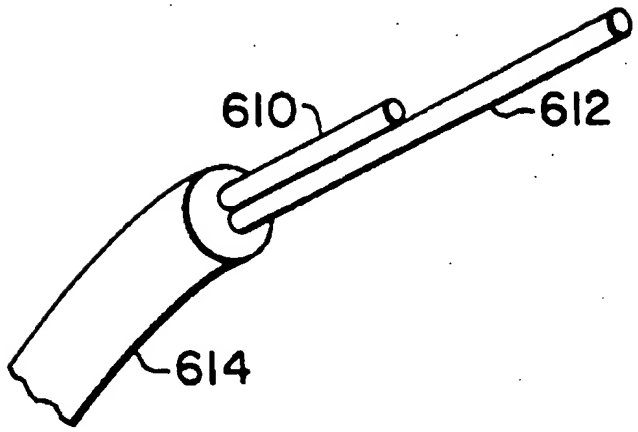
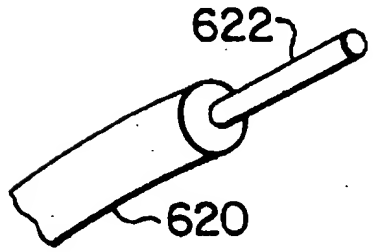


FIG. 6B



DOUBLE CHAMBER TISSUE EXPANDER

FIELD OF THE INVENTION

The present invention relates to a device for the expansion of tissue, in particular, to an implantable tissue expander which provides for a liquid solution to diffuse into the subcutaneous tissue in contact with or proximity to the expansile (or expansible) surface of the implanted device.

BACKGROUND OF THE INVENTION

In the field of reconstructive surgery, tissue expanders play an important role. Mechanical tissue expansion is a means to increase the dimensions of tissue. The technique is commonly used in surgery involving the implantation of permanent prosthetics, such as breast reconstruction, and reconstructive surgery in which additional skin is required, such as burn reconstruction.

Tissue expansion for cosmetic or reconstructive surgery has two components: dissection of the skin and subdermal elements from the underlying tissue, to create a cavity, and expansion of an expander device placed in the cavity to stretch the surrounding tissues, particularly the skin. The dissection process may continue after implantation of an expander, thus recruiting additional tissue to stretch in response to the force of the expander.

The expansion of tissue can be a painful procedure, require long time periods, or both. Furthermore, the success of a tissue expansion procedure will depend on the characteristics of the individual's skin, e.g., whether it is elastic and pliable, youthful, and other factors. Tissue expansion is based on the principle that skin and subdermal elements, including nervous tissue and vascular structures, stretch in response to expansion of an enlarging mass. The stretching results in an increase in surface area of the skin and other tissues. However, prior to the instant invention, there has been no concurrent pharmacological component of tissue expansion devices.

U.S. Pat. No. 2,499,045 to Walker et al., relates to an ano-rectal dilator and medicator. The invention consists of a tube with apertures, which is connected to an air inflation device, a bladder element enclosing the apertured portion of the tube, a non-expandable fabric form element that defines a maximum expansion size surrounding the bladder element, and a perforated resilient casing element surrounding the form element. A quantity of a treating agent can be interposed between the form element and the perforated casing element so that when the device is inflated, the treating agent is forced outwardly through the perforations and into contact with the affected areas of the rectal passage. The device does not include a chamber for holding the treatment agent, nor does it provide for replacing treating agent in situ.

U.S. Pat. No. 3,934,274 to Hartley, Jr., relates to a surgically implantable tissue augmentation prosthesis for mammary augmentation. The device comprises an outer sac and an inner capsule which is contained within the outer sac and occupies less than the entire volume of the outer sac. A gel or liquid is sealed within the inner capsule. The outer sac is filled with a liquid using a filling valve. Liquid in the outer sac may be withdrawn in order to deflate the prosthesis in response to spherical contracture.

U.S. Pat. No. 4,685,447 to Iversen et al., relates to a tissue expander system including a flat one-piece molded tissue expander, a connecting tube, and an injection port. A piece of non-stick fluorocarbon material can be used to prevent sticking of the tissue expander material during expansion. A

Dacron mesh can be embedded in the tissue expander to provide for directional expansion.

U.S. Pat. No. 4,800,901 to Rosenberg, relates to a balloon type tissue expander which is inflated through a tube connected to the balloon and extending through an opening in the skin. In addition, there is a separate drain tube attached to or surrounding the inflation tube. The drain tube allows fluid, which may accumulate at the implantation site, to exit through an opening in the skin. An irrigation tube which is connected to the drain tube or inside the drain tube may also be included. This permits an irrigating liquid to be introduced into the implantation site of the balloon.

U.S. Pat. No. 4,984,585 to Austad, relates to a tissue expander comprised of an inflatable envelope, which can be separably mounted on a more rigid base, and a connector tube system which introduces fluid into the envelope. This invention provides for cutting the base into any desired shape, and conforming the expandable envelope to that shape.

U.S. Pat. No. 5,005,591 to Austad, relates to a self-inflating tissue expander. The tissue expander has a window portion which is highly permeable to extracellular water, however, the remaining portion is generally impermeable to water. The expander contains an osmotic agent that absorbs extracellular water. Absorption of water causes inflation of the implant.

Adjunctive Agents to Facilitate Rapid Tissue Expansion by Netscher et al. (Ann. Plast. Surg. 23:412, 1989), relates to a study of the effects of hyaluronidase, colchicine and prostaglandin E_2 on tissue expansion using rodent models. The agents were delivered into the tissue surrounding the implanted tissue expander by use of an intravenous catheter mounted on the circumference of the tissue expander. Infusion of a chemical agent was entirely independent of the expansion process.

The citation of any reference herein should not be deemed an admission that such reference is available as prior art to the invention.

SUMMARY OF THE INVENTION

The inventor has recognized a need in the art for an integrated tissue expander-expansion promoter delivery system to provide for greater comfort as well as facilitate and improve tissue expansion procedures.

Accordingly, the present invention provides a dual chamber tissue expansion device for subcutaneous implantation and delivery of a tissue expansion promoter in a patient. The device comprises an implantable expansion and delivery means comprising an expandable outer bladder prepared from a porous material capable of discharging an infusion solution therethrough, which defines an infusion chamber; and an expandable inner bladder disposed within said outer bladder and prepared from a non-porous material, which defines an expansion chamber, said inner bladder serving to effectuate the majority of the expansion of said expansion and delivery means. The device also includes means for delivering said infusion solution adapted for location external to said patient in use, and in fluid registry with said outer bladder, and means for inflating said inner bladder adapted for location external to said patient in use, and in fluid registry with said inner bladder. Preferably, the device comprises means for preventing adhesion of the outer membrane of the expansion chamber to the inner wall of the infusion solution chamber, such as texturing of the surfaces of each bladder that may be in contact or by providing a mechanical spacing member.

After implantation of the device subcutaneously, an infusion solution can introduced and removed from the outer bladder or infusion chamber. This allows for replacement of one infusion solution with another rapidly, or for increasing or decreasing the infusion rate by controlling pressure. Furthermore, fluid that accumulates in the tissue in contact with the tissue expansion device can be removed by applying suction to the infusion chamber.

Inflation of the inner bladder, or expansion chamber, can be accomplished by introducing a fluid into the expansion chamber. Fluid can be removed from the expansion chamber to deflate the device, e.g., to decrease pressure or prior to removal.

In a preferred embodiment, said inner and outer bladders are attached to a substantially non-stretchable and non-expandable member. In this embodiment, expansion of the device occurs in all directions except those bounded by this non-stretchable and non-expandable member. Generally, upon implantation, this member, which may be termed a backplate, is placed in contact with tissue, such as muscle or bone, where expansion is not desired.

As the expansion fluid fills the expandable inner bladder, the non-porous material expands. This expansion exerts a pressure forcing the infusion solution out of the infusion solution chamber, through the expandable porous material, and into the tissue surrounding and in contact with the porous material. In another embodiment, injection of the infusion solution under pressure can force the infusion solution out of the infusion solution chamber, through the expandable porous material, and into the tissue surrounding and in contact with the porous material. The pressure on the infusion solution, whether by expansion of the expansion chamber or injection through the liquid transport means, provides one mechanism for controlling the rate and depth of infusion of the infusion solution into tissues. Moreover, infusion occurs into all of the tissue in contact with the porous material that makes up the wall of the infusion chamber of the expander, which is the expansile surface of the expander.

The present invention advantageously provides for infusion of a promoter of tissue expansion, i.e., one or more agents to facilitate the tissue expansion process. For example, the infusion solution may be saline or water for hydrodissection of the surrounding tissue. The infusion solution may contain an extracellular matrix digestive enzyme, such as hyaluronidase, that hydrolyzes one or more components of the extracellular matrix, which makes up the "glue" of the connective tissue; an anesthetic, such as lidocaine or bupivicaine, to relieve the pain associated with expansion; antibiotics, to prevent or treat an infection that may occur with any invasive procedure; a growth factor, in particular epidermal growth factor, to facilitate tissue growth following expansion; or an agent that inhibits one or more of the conditions of fibrosis, capsule formation, or scarring, such as a steroid, e.g., dexamethasone, or an anionic polymer, such as dextran sulfate. Two or more agents can be infused simultaneously or serially.

As noted above, the infusion chamber can serve as a reservoir for any accumulated liquid or fluid in the tissue around the expander. Such liquid or fluid will naturally flow through the pores of the porous material, and can be removed from the infusion chamber by applying suction through the liquid transport means (e.g., using the same means as for removing infusion solution). Applying suction to the infusion chamber will increase the rate of removal of accumulated liquid or fluid from the tissue.

In another embodiment, a drain may be inserted coaxially with, adjacent to, or in proximity to the infusion solution liquid transport means and the expansion fluid transport means for collection of accumulated fluid from around the expander and removal of the fluid from the tissue.

The present invention satisfies the need in this field for a tissue expansion device which permits various infusion solutions to be introduced into an implanted device without having to remove the device from the patient's body. The expansion of tissue can be very painful procedure. An advantage of the present invention is that it allows expansion to occur while simultaneously infusing the tissue area with, for example, anesthetic, to alleviate pain, hyaluronidase, to facilitate tissue dissection that accompanies expansion, or both. This advantage is important since the use of hyaluronidase can hasten the expansion process, and anesthetics can make the expansion process more comfortable for the patient. Furthermore, different infusion solutions can be used at different stages of the expansion process to augment each stage, for example, use of anesthetic upon insertion, a hydrolytic enzyme during expansion, and a growth factor to induce growth of the expanded skin. Infusion of such solutions is particularly beneficial when administered locally to all of the tissue in contact with the expansion device and with each subsequent expansion.

An object of this invention is to provide a device which expedites the expansion of tissue.

Another object of this invention is to provide a device which makes tissue expansion more comfortable for the patient.

Yet another object of the invention is to permit different infusion solutions to be introduced into all of the tissue in contact with the expanding wall of a tissue expander device requiring removal of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be better understood by reference to the drawings, which are schematic and are not drawn to scale.

FIG. 1A is a schematic plan view of a specific embodiment of the DOUBLE CHAMBER TISSUE EXPANDER which is round and expands uniformly in all directions, i.e., spherically.

FIG. 1B is a full sectional side view of an alternate embodiment of the DOUBLE CHAMBER TISSUE EXPANDER having a backing member, which is round but expands hemispherically.

FIG. 2 is a schematic plan view of an embodiment of the invention in which the DOUBLE CHAMBER TISSUE EXPANDER has a square rectangular shape.

FIG. 3 is a schematic plan view of an embodiment of the invention in which the DOUBLE CHAMBER TISSUE EXPANDER has rod shape.

FIG. 4 is a schematic plan view of an embodiment of the invention in which the DOUBLE CHAMBER TISSUE EXPANDER has a triangular shape.

FIG. 5A is a schematic drawing of the infusion solution liquid transport means and the expansion fluid liquid transport means having separate injection ports, which are shown in a side view.

FIG. 5B is a schematic drawing of an embodiment in which there is a single injection port, shown in plan view, having a single hemisphere divided by a wall providing for separate injection of the infusion solution and the expansion fluid.

FIG. 6A is a schematic drawing of an embodiment wherein the tube for the infusion solution liquid transport means and the tube for the expansive fluid transport means are encased in an outer sleeve.

FIG. 6B is a schematic drawing of an embodiment wherein the expansion fluid tube is encased in infusion solution tube, i.e., the tubes are arranged coaxially.

DETAILED DESCRIPTION OF THE INVENTION

The present invention, for simultaneous expansion and delivery of a tissue expansion promotor to tissue, is comprised of an expandable infusion solution chamber (infusion chamber) which is defined by a stretchable porous material or wall. Within the infusion chamber is an inner bladder, i.e., an expansion fluid chamber (expansion chamber), which is isolated by a stretchable non-porous material, or wall, from the infusion chamber. Solutions are introduced and removed from the infusion chamber by a liquid transport means. Fluids are introduced and removed from the expansion chamber by a fluid transport means.

The term "tissue expansion" is used generally to describe the increase in tissue dimensions under the influence of a slowly enlarging mass beneath it. Tissue expansion may occur naturally or as a result of mechanical force. Natural tissue expansion occurs as a result of, for example, weight gain, tumor growth, and pregnancy. Tissue expansion by mechanical force is now a recognized modality of treatment in reconstructive surgery; as used herein, the term "tissue expansion" refers to expansion by mechanical force exerted by an implanted device.

As used herein, the term "hydrodissection" relates to the installation of an aqueous solution, such as saline or water, in soft tissues. The hydrodynamic force of the aqueous solution facilitates separation of the skin from the underlying tissue. Hydrodissection can facilitate open dissection, and can be implemented according to the instant invention to facilitate expansile dissections as well.

The outer bladder, or infusion chamber, is prepared from a stretchable non-porous material. The term "stretchable porous material" refers to a material which allows the infusion solution to pass from the infusion chamber into the tissue surrounding the implanted tissue expander, and which can stretch, i.e., increase its total area, during expansion of the device. The term "stretch" refers to the ability of the porous material to increase size in the dimensions of its plane; the material does not increase significantly in thickness, however. The rate of infusion can be controlled, in part, by choosing the number and size of the "pores" in the porous material. In one embodiment, the stretchable porous material has uniformly sized pores, e.g., produced in the material manufacturing process, that allow fluid to pass. Alternatively, the stretchable porous material may be a non-porous material that has been perforated, e.g., with a laser, pin or needle pricks, or by cutting. The expandable porous material should be biocompatible. In a preferred embodiment, the expandable porous material is prepared from perforated silicone rubber. Other expandable materials for use in surgical procedures and implantation in animals, particularly humans, may be used.

The porous material can be fabricated to contain pores or micropores, or it may be a non-porous material that is modified by puncturing to make small cuts, holes, or pores, e.g., with a needle. An advantage of using a porous material is that the pores create a surface texturing effect on the exterior of the implant. Surface texturing, or creating a roughened surface on an implant, helps prevent formation of a thickened capsule. Although this is not important to tissue expansion, it is important when such an expansion device is subsequently used as an implant.

The inner bladder, or expansion chamber, is prepared from a stretchable non-porous material. The term "stretchable non-porous material" refers to a material which is essentially non-porous, i.e., which prevents significant dispersion or diffusion of fluids through or across the material. Examples of suitable materials include silicone rubber, and derivatives thereof. Other suitable materials which are appropriate for surgical procedures and implantation in animals, particularly humans, may be used. "Stretchable" is used as defined above in connection with the non-porous material. The material should be strong enough to withstand expansion of the chamber without cracking or significant leaking.

According to the invention, the inner bladder and outer bladder do not adhere to each other. In a particular aspect, the invention provides means for preventing adhesion of the outer surface of the expansion chamber to the inner surface of the infusion chamber. For example, if the walls of both chambers are prepared from silicone rubber, upon contact the walls may adhere to each other. Preventing such adhesion can be achieved by manufacturing each chamber from materials that do not adhere to each other on contact. A means for preventing adherence is to prevent contact mechanically, e.g., with use of a mechanical spacing member. For example, appropriately sized, inert spheres or a matrix that fits between the chambers can be included. Alternatively, either the outer surface of the expansion chamber, or the inner surface of the infusion chamber, or both, can be textured.

As used herein, the term "infusion solution" refers to any solution introduced into the infusion chamber to be eluted from the pores of the porous membrane when sufficient pressure is exerted by the expanding non-porous material or by injection pressure. The infusion solution may contain one or more agents that can facilitate tissue expansion. Examples of such agents include antibiotics, anesthetics, extracellular matrix digestive enzymes, growth factors, e.g., epidermal growth factor (EGF), fibroblast growth factor (FGF), platelet-derived growth factor (PDGF), and angiogenic growth factor, and agents that inhibit fibrosis, capsule formation and/or scar formation.

Preferred antibiotics include those effective against staphylococci, such as but not limited to methicillin and vancomycin. Generally, antibiotics are administered prophylactically, since if a bacterial infection develops around the implanted expander, usually the expander is removed from the subject.

As used herein, the term "extracellular matrix digestive enzyme" refers to an enzyme that digests a component of the extracellular matrix. One such enzyme is hyaluronidase. Enzymes that digest glycosaminoglycans or proteoglycans, can also be used, such as, but not limited to, chondroitinase, keratanase, and the like.

As used herein, the term "agent that inhibits fibrosis, capsule formation, or scar formation" includes but is not limited to steroids, such as dexamethasone, and anionic polymers, such as dextran sulfate.

The term "expansion fluid" refers to any fluid introduced into the expansion solution chamber in order to expand the expandable non-porous material. Examples of suitable expansion solutions include, but are not limited to saline, buffered saline, water and air.

A specific embodiment of the invention is shown in FIG. 1A. The dual chamber tissue expansion device, **100**, may be subcutaneously implanted within a patient. The device contains an infusion chamber, **102**, defined by a stretchable porous material, **104**; an expansion chamber, **106**, located within the infusion chamber but isolated from the infusion chamber by a stretchable non-porous material, **108**; an infusion solution liquid transport means, **110**; and an expansion fluid transport means, **112**. The infusion solution transport means and expansion fluid transport means may be silicon tubes, or other bio-compatible materials formed in tubular shape. In this embodiment, the infusion solution transport means and expansion fluid transport means are tube arranged coaxially, in which the expansion fluid tube, **112**, is inside the infusion solution tube, **110**.

Following implantation of the dual chamber tissue expander, expansion fluid is introduced to the expansion chamber through the expansion fluid transport means, **112**. As the expansion chamber fills with expansion fluid, the expansion chamber, **106**, expands, and the non-porous material, **108**, stretches. The expansion fluid transport means, **112**, may also be used to remove expansion fluid from the expansion solution chamber to facilitate removal of the dual chamber tissue expander, or reduce expansion pressure, if either are desired.

The pressure exerted by the expanding expansion chamber pressurizes the infusion solution, which is introduced to the infusion chamber, **102**, through the infusion solution transport means, **110**. In another embodiment of the invention, the pressure exerted by the injection of infusion solution into the infusion chamber, by use of the infusion solution transport means, pressurizes the infusion solution. In either cases, the infusion solution pressure forces the infusion solution through the porous material, **104**, and into the tissues in contact with or proximal to the expander.

In a preferred embodiment of the present invention, the infusion solution is saline, to provide for hydrodissection of the connective tissue matrix. For example, the infused solutions may be 0.15M NaCl, or buffered 0.15M NaCl.

In other embodiments, lidocaine, hyaluronidase or both may be present in the infusion solution.

The infusion solution liquid transport means, **110**, may also be used to remove an infusion solution from the infusion solution chamber, **102**, if that is necessary. As a result, the infusion solution may be changed without removing the implanted dual chamber expander from the patient's body.

A particular advantage of the invention is the flexibility it provides with respect to the infusion of agents to facilitate tissue expansion. In particular, one or more agents can be infused together. Alternatively, different agents can be infused serially, if that is desired. For example, the initial infusion solution may comprise hyaluronidase and lidocaine in a buffered saline solution. This infusion solution would lead to hydrodissection and digestion of the connective tissue matrix, with local anesthesia to alleviate discomfort and pain. Additionally, in the immediate postoperative period, an antibiotic may be infused to prevent the onset of an infection. Finally, after the skin is stretched, infusion of a growth factor may provide for growth of new tissue, yielding a robust expanded tissue ready for use in reconstructive surgery.

In another embodiment of the present invention, as shown FIG. **1B**, the double chamber tissue expander device, **101**, which includes a porous outer wall, **104**, that defines the infusion chamber, **102**, within which the expandable inner bladder prepared from a non-porous material, **108**, which defines the expansion chamber, **106**, is mounted to a rigid backplate, **109**. The use of a backplate, **109**, permits expansion in all direction except against the backplate, i.e. , the device expands hemispherically. The backplate does not contain pores, so no infusion solution elutes in that direction. Examples of materials suitable for the backplate include a thick silicone material with fibrous synthetic mesh or net within the silicone to give strength and prevent stretching. In this embodiment, the expansion fluid transport means (tube), **112**, is arranged coaxially within the infusion solution transport means (tube), **110**.

In addition to having a preferred round or circular shape yielding a sphere or hemisphere (if there is a backplate) upon inflation, a device of the invention may be square or rectangular, (FIG. **2**), **200**, rod shaped (FIG. **3**), **300**, or triangular (FIG. **4**), **400**. Such alternatives may be useful where the shape can provide an advantage. For example, a rod-shaped device can be used to expand tissue along the length of a limb, e.g., for reconstruction of a gash, burn or other injury running the length of the limb.

FIG. **5A** is a detail drawing of the infusion solution liquid transport tube, **110**, with infusion solution delivery means, which is an injection port, **114**, and the expansion fluid transport tube, **112**, with inflating means, which is a separate injection port, **116**. One end of each tube is connected to the respective chamber (not shown here). The other end is connected to an injection port, e.g., as described in U.S. Pat. No. 4,685,447 to Iversen et at., which is specifically incorporated herein by reference. The tubes are adapted to pass through an opening in the skin when the device is implanted. In FIG. **5A**, the injection ports, **114** and **116**, are separate. In this embodiment, the tubes are arranged coaxially. Therefore, sealing means, **500**, are provided to allow for exit of the internal expansion fluid tube to connect to its injection port without causing a leak in the injection solution tube. For example, the tubes can be heat sealed, or a sealant, such as silicone, applied to form a seal.

FIG. **5B** is another embodiment, wherein a single injection port, **118**, having two separate hemispheres, one for injection or withdrawal of an infusion solution, **120**, and another for injection or withdrawal of an expansion fluid, **122**, mounted on a base, **124**, is used. Such a dual injection port can be prepared by modifying a single injection port by including a wall, **126**, fabricated from the same material as the bulb of the injection port, dividing the hemisphere in half. Again, since the tubes are arranged coaxially, sealing means, **500**, as described above, are provided.

FIG. **6A** is a detail drawing of one embodiment wherein the infusion solution tube, **610**, and the expansion fluid tube, **612**, are encased in an outer sleeve, **614**. The outer sleeve provides for contact of a single surface with the skin opening through which the tubes extend. Accordingly, the outer sleeve must be prepared from a biocompatible material. An example of suitable outer sleeve material is silicone. Clearly, in this embodiment, no sealing means, as shown in FIGS. **5A** and **5B**, is required.

FIG. **6B** is another embodiment wherein the infusion solution tube, **620**, is encases the expansion fluid tube, **622**. This embodiment is shown in FIGS. **1–5** as well.

The specific embodiments disclosed above are not intended to limit the present invention. It is recognized that changes may be made in the process and apparatus specifically described herein without departing from the scope and teachings of the present invention.

Various publications and patents are cited in the Specification, each of which is specifically incorporated herein in its entirety.

What is claimed is:

1. A tissue expansion device for subcutaneous implantation and delivery of a tissue expansion promoter in a patient comprising:

an expansion and delivery means for subcutaneous implantation and tissue expansion comprising an expandable outer bladder prepared from a stretchable porous material capable of discharging an infusion solution therethrough, and

an expandable inner bladder disposed within said outer bladder and prepared from a stretchable non-porous material, which inner bladder and outer bladder are non-adherent, said inner bladder serving to effectuate the majority of the expansion of said expansion and delivery means;

wherein said inner and outer bladders are attached to a substantially non-stretchable and non-expandable rigid backplate member;

means for delivering said infusion solution adapted for location external to said patient in use, and in fluid communication with an interior of said outer bladder; and

means for inflating said inner bladder adapted for location external to said patient in use, and in fluid communication with an interior of said inner bladder.

2. The device of claim 1 further including means for preventing adhesion of the inner bladder to the outer bladder.

3. The device of claim 1 further including first liquid transport means associated with said infusion solution delivering means, for delivering said infusion solution to said outer bladder, and a second fluid transport means associated with said inflating means for introducing and removing an expansion fluid into and out of said inner bladder.

4. The tissue expansion device according to claim 1 in which the stretchable porous material is perforated silicone.

5. The tissue expansion device according to claim 1 wherein said outer bladder contains an infusion solution, and said infusion solution comprises an agent selected from the group consisting of an antibiotic, an anesthetic, an extracellular matrix digestive enzyme, a growth factor, and an agent that inhibits one or more of the conditions of fibrosis, capsule formation, or scar formation.

6. The tissue expansion device according to claim 1 in which said outer bladder contains an infusion solution selected from the group consisting of water, buffered saline, and saline.

7. The tissue expansion device according to claim 1 in which stretchable non-porous material is silicone.

8. The tissue expansion device according to claim 1 wherein said inner bladder contains an expansion fluid selected from the group consisting of buffered saline, saline, water, and air.

9. The tissue expansion device according to claim 1 in which said infusion solution delivery means is tubular wherein one end is in liquid communication with the interior of said outer bladder, and the opposite end extends to a first injection port.

10. The tissue expansion device according to claim 1 in which said inflating means is tubular wherein one end is in fluid communication with the interior of said inner bladder, and the opposite end extends to a second injection port.

11. The tissue expansion device according to claim 1 in which said infusion solution delivery means is tubular wherein one end is in liquid communication with the interior of said outer bladder and the opposite end extends to a first injection port; and the inflation means is tubular wherein one end is in fluid communication with the interior of said inner bladder and the opposite end extends to second injection port.

12. The liquid transport means of claim 11 in which said inflation means is located co-axially inside said infusion solution delivery means.

13. The tissue expansion device of claim 1 which is round.

14. The tissue expansion devise of claim 13 which is round.

* * * * *

US005935098A

United States Patent [19]

Blaisdell et al.

[11] Patent Number: 5,935,098

[45] Date of Patent: Aug. 10, 1999

[54] **APPARATUS AND METHOD FOR ACCESSING AND MANIPULATING THE UTERUS**

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[73] Assignee: **Conceptus, Inc.**, San Carlos, Calif.

[21] Appl. No.: **08/772,707**

[22] Filed: **Dec. 23, 1996**

[51] **Int. Cl.**[6] **A61M 31/00**; A61M 25/00

[52] **U.S. Cl.** **604/55**; 604/101; 606/193

[58] **Field of Search** 606/1, 191, 193, 606/194, 195, 158; 604/55, 174, 96–101, 178

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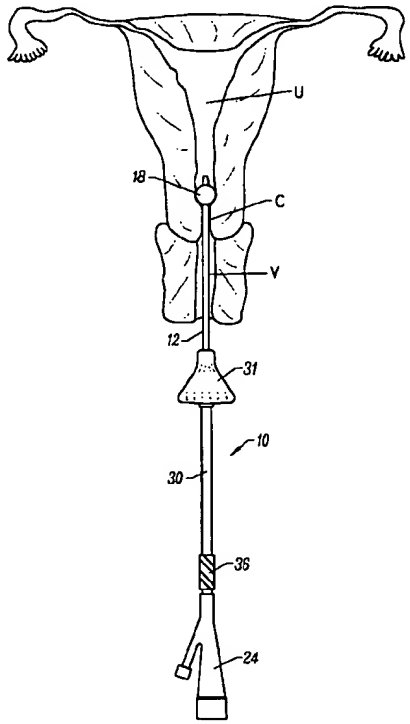
Primary Examiner—Michael Buiz
Assistant Examiner—William W. Lewis
Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

A uterine access catheter system comprises an inner catheter and a sleeve catheter slidably disposed over the inner catheter. The inner catheter is a balloon catheter having an elastomeric balloon near its distal end and suitable for performing hysterosalpingography procedures. The sleeve catheter includes an occluding member near its distal end, and the inner catheter and outer catheter may be used together to seal against and engage the cervix of a patient undergoing hysterosalpingography or other genealogical procedures. The sleeve catheter is locked to the inner catheter, typically relative by relative rotation of the two catheters. The occluding member may be detachable and reusable. Means may be provided for drawing a vacuum between the occluding member and the balloon to further engage the cervical os.

26 Claims, 10 Drawing Sheets



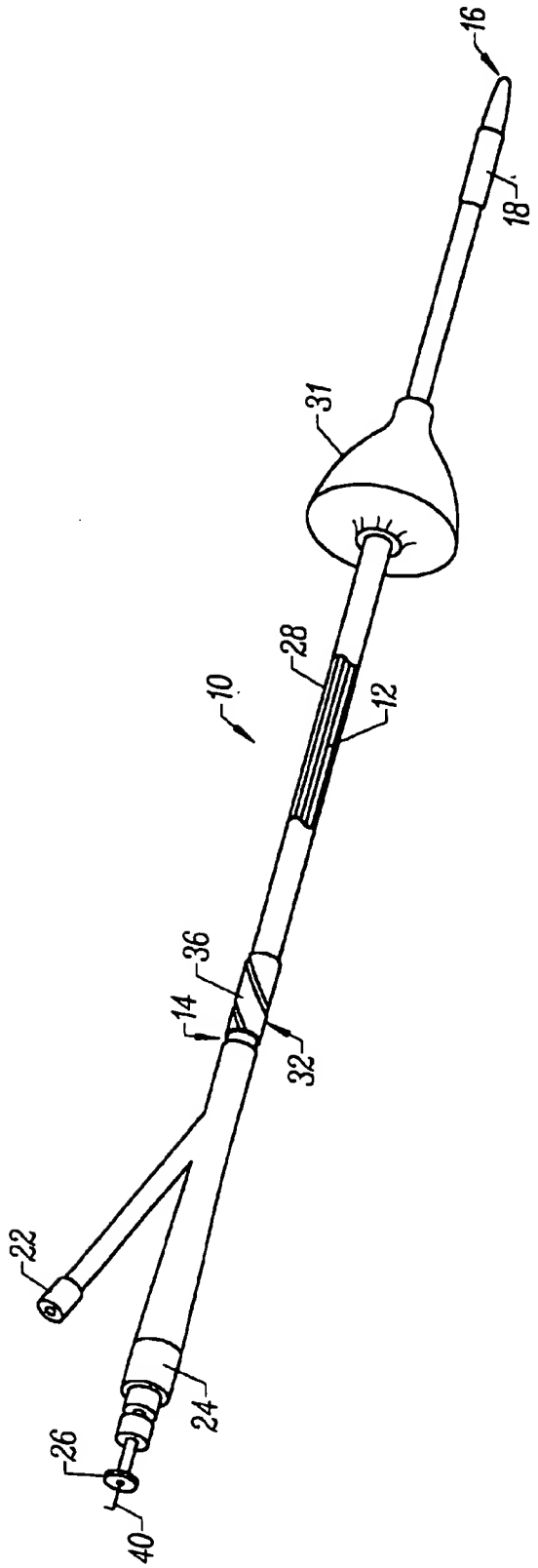


FIG. 1

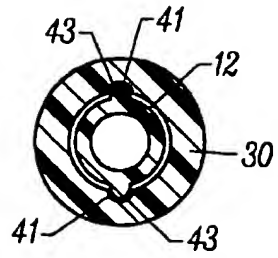


FIG. 1B

FIG. 1A

FIG. 1C

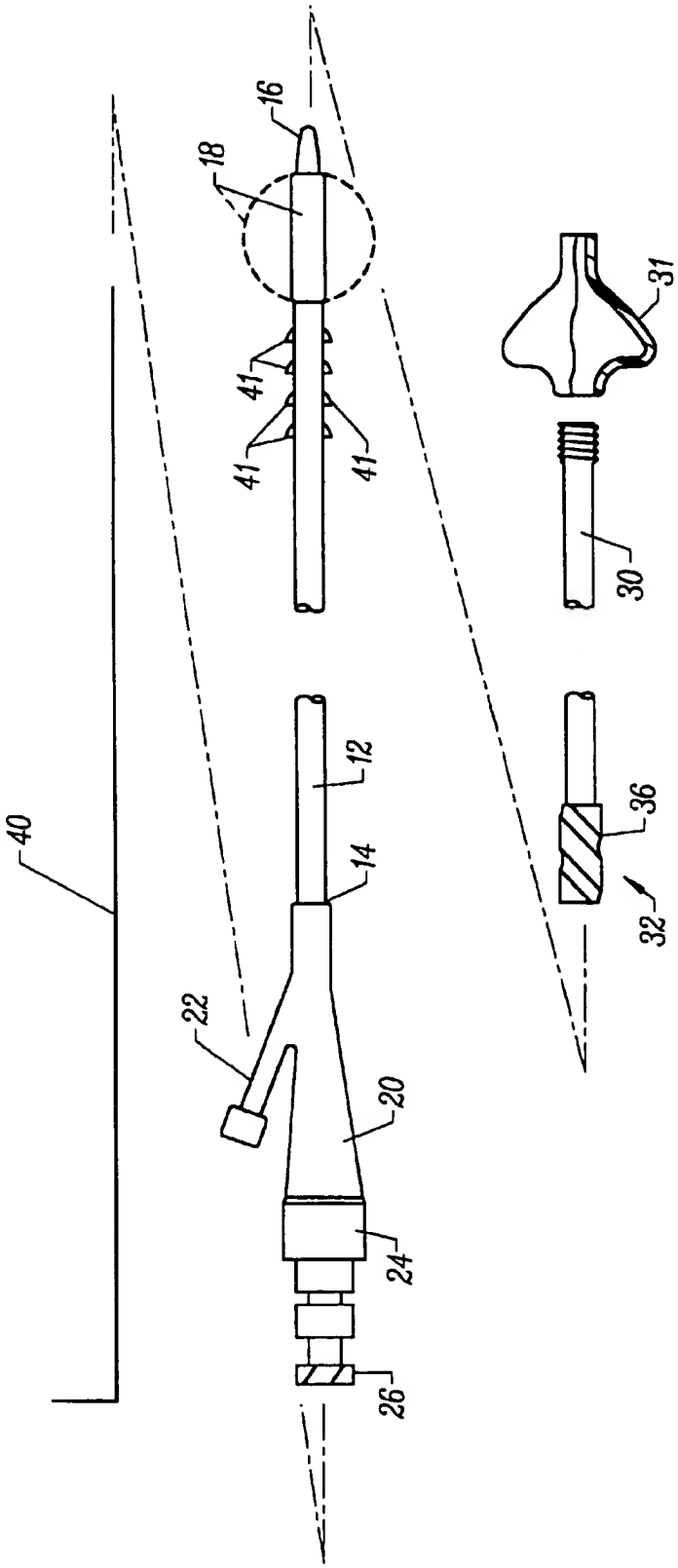


FIG. 2

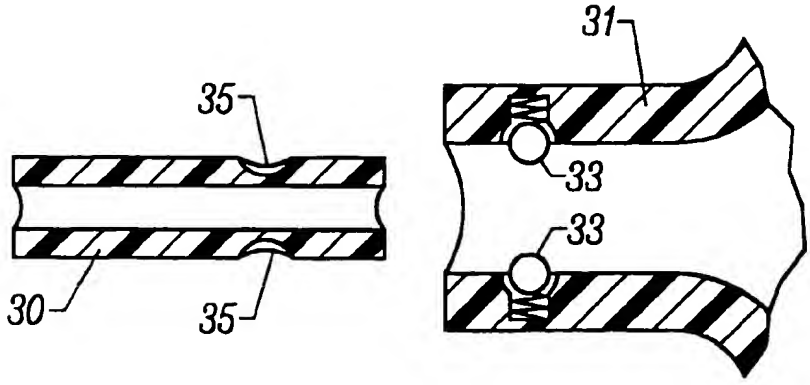


FIG. 2A

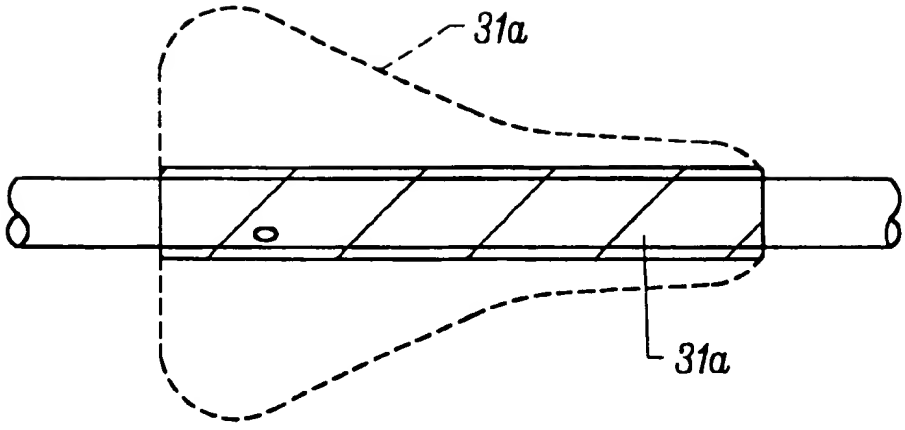


FIG. 2B

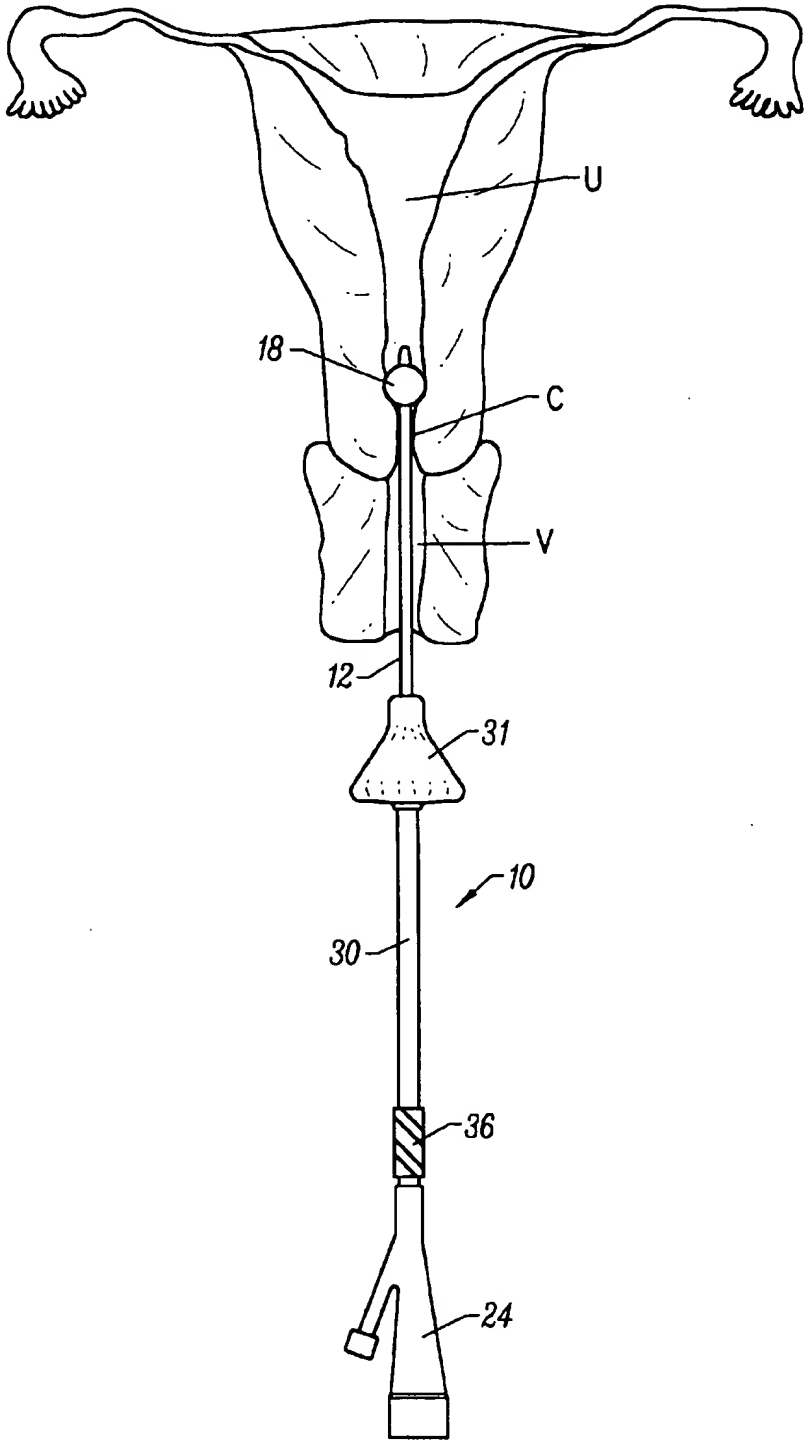


FIG. 3A

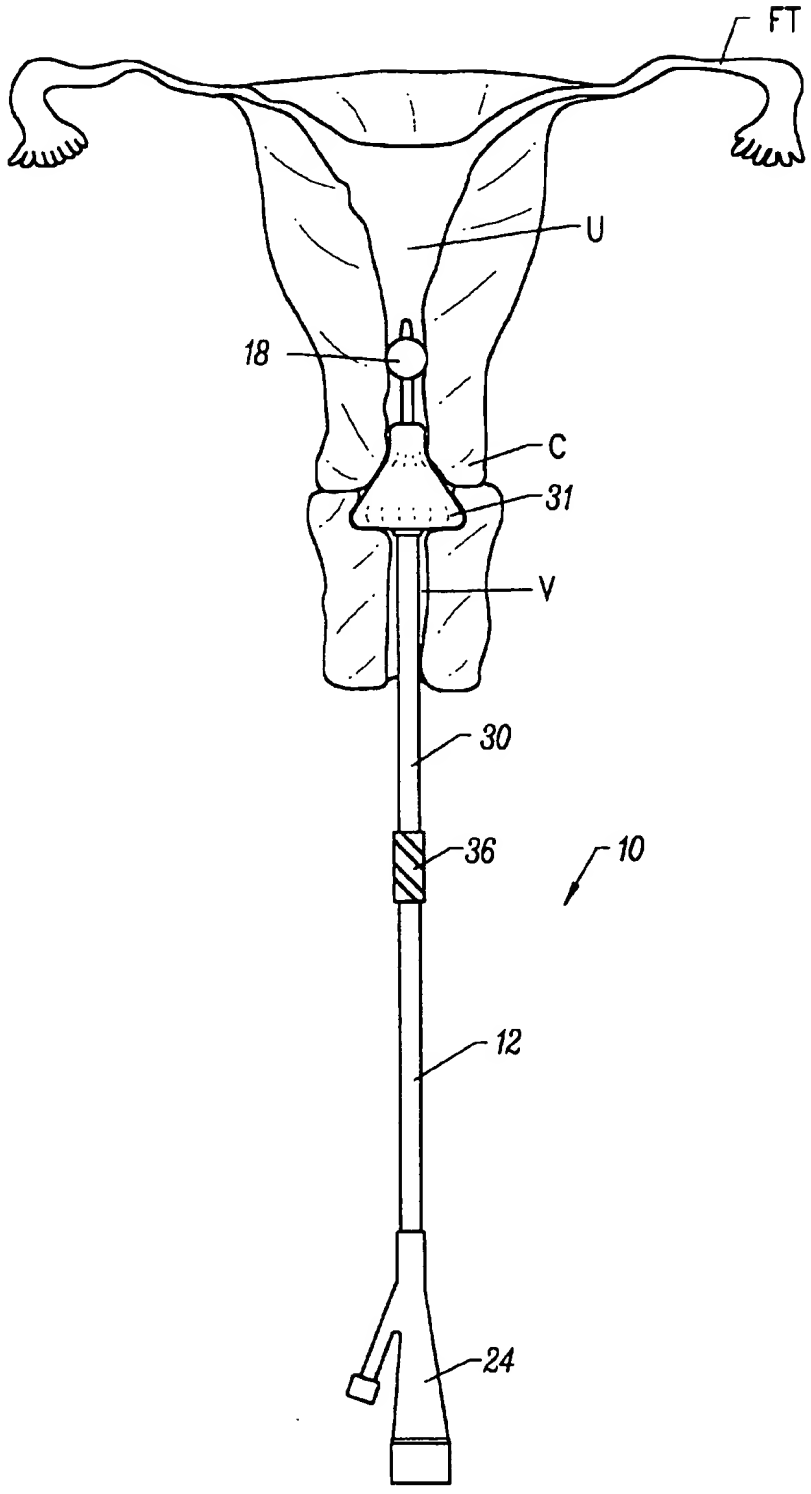


FIG. 3B

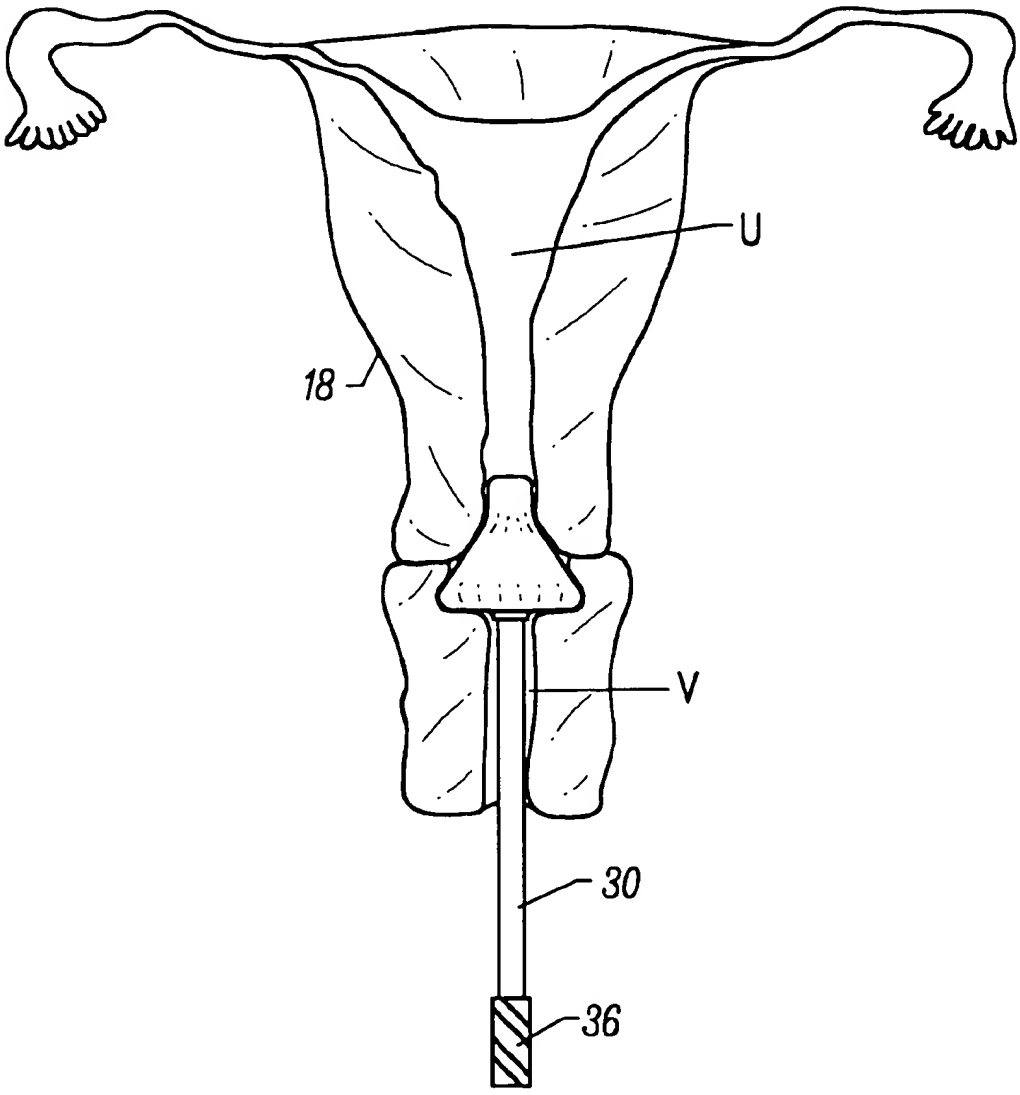


FIG. 3C

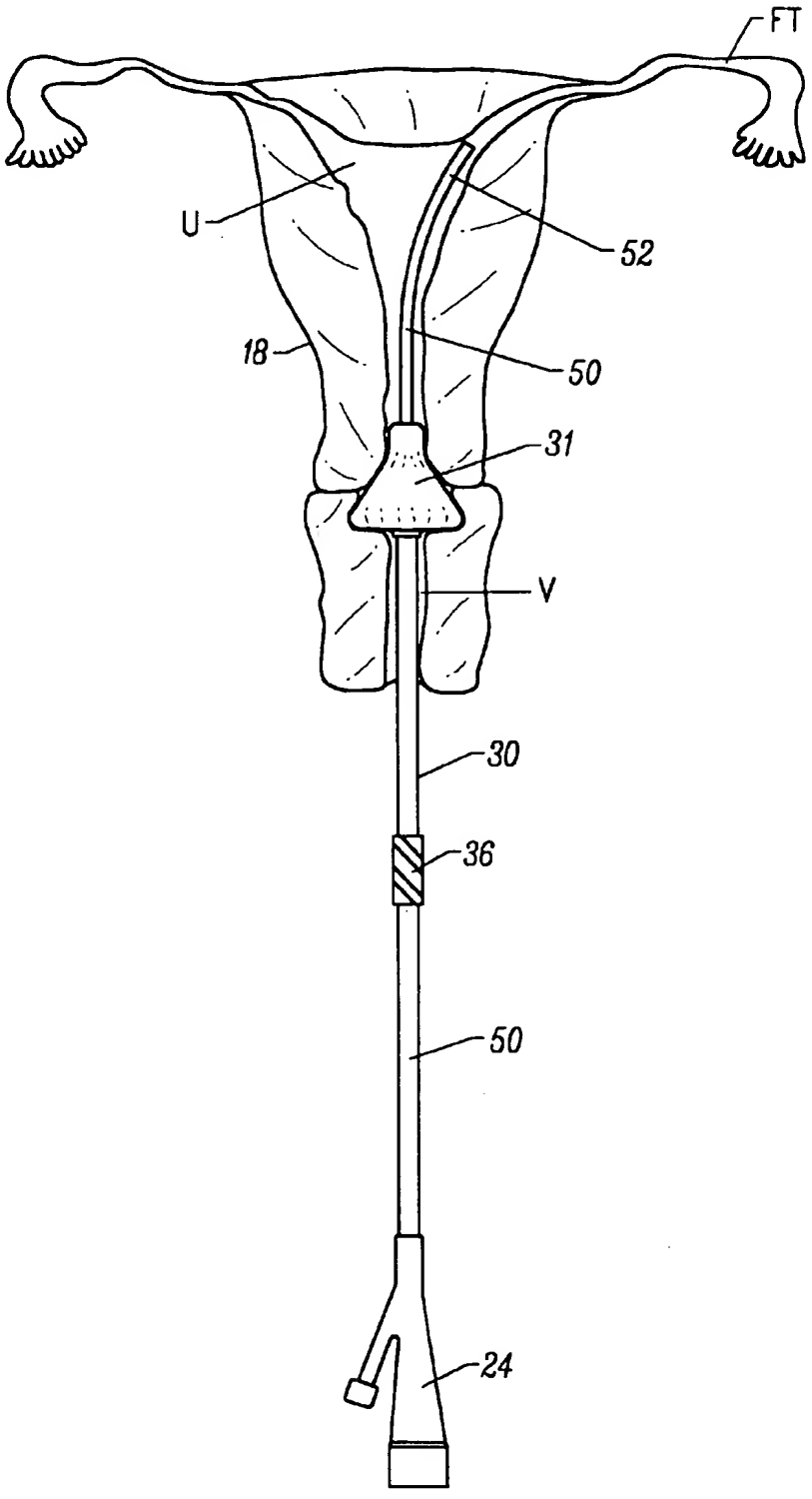


FIG. 3D

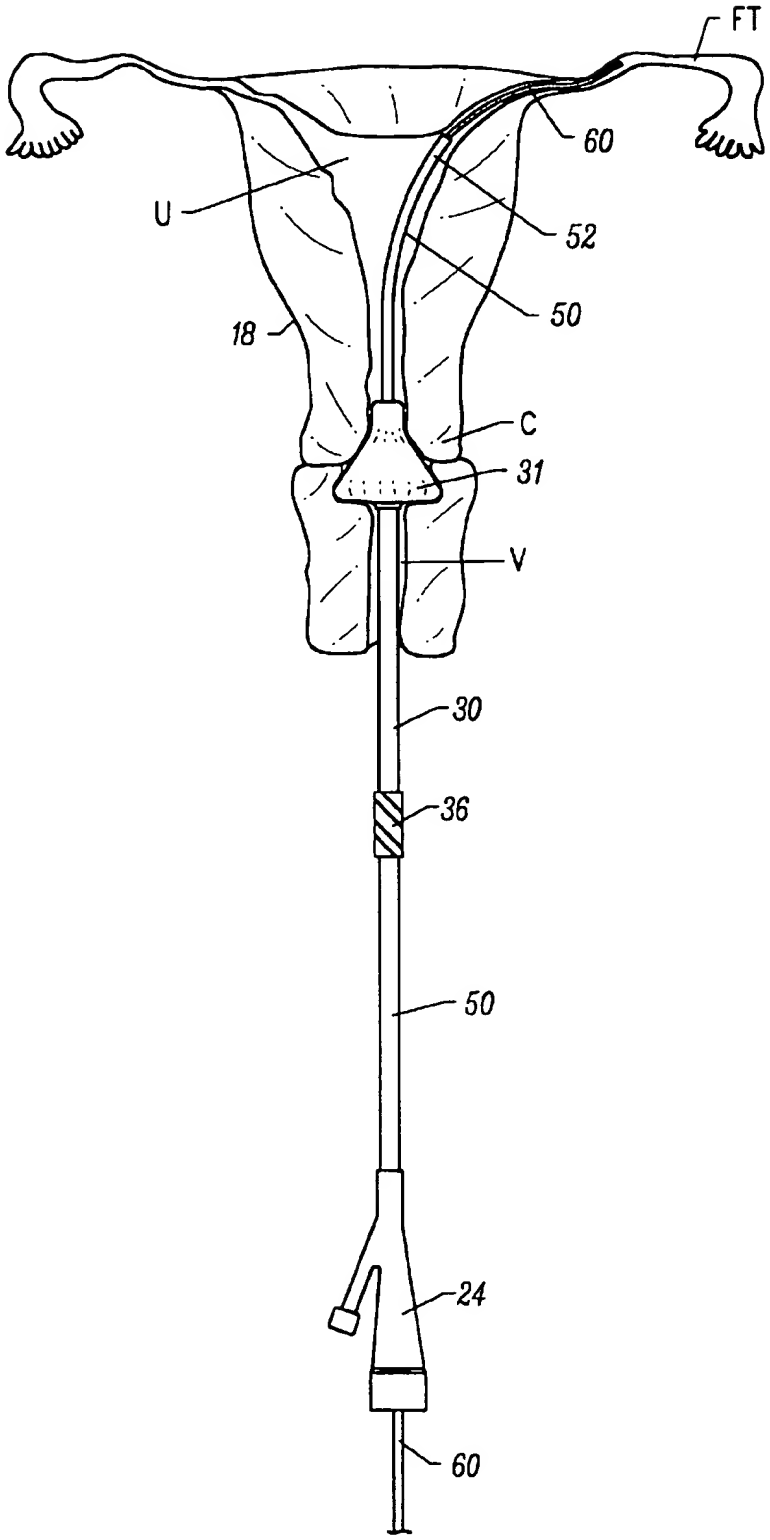


FIG. 3E

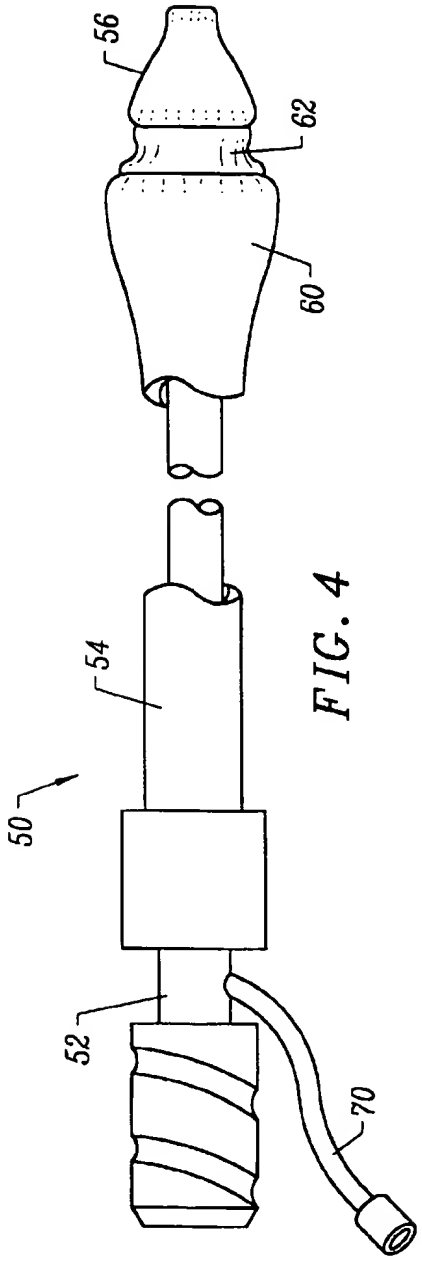


FIG. 4

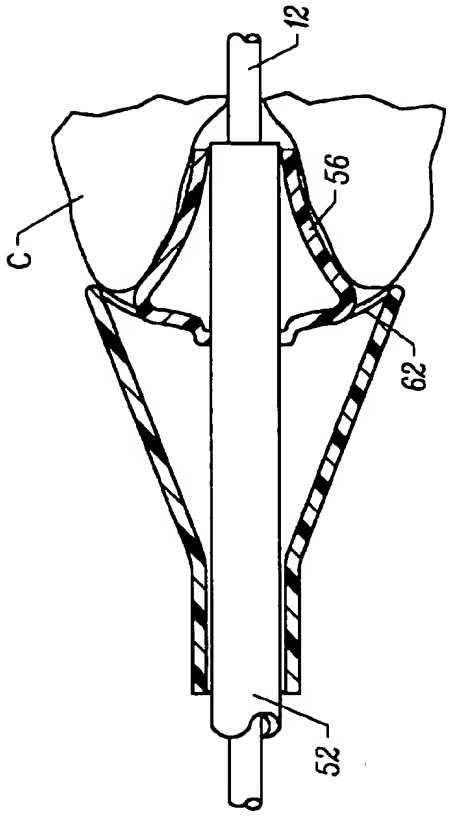


FIG. 6

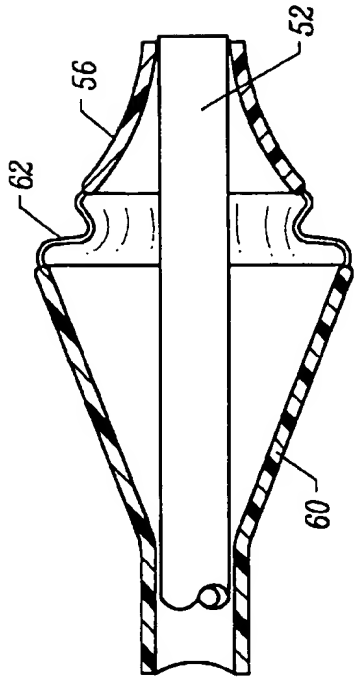


FIG. 5

APPARATUS AND METHOD FOR ACCESSING AND MANIPULATING THE UTERUS

The subject matter of the present application is related to copending application Ser. No. 08/772,395 (attorney docket No. 16355-003100), filed on the same day as the present application, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to methods and apparatus for accessing the uterus and optionally the fallopian tubes of a patient. More particularly, the present invention relates to a uterine access catheter system and method which provide for both uterine access and manipulation.

Diseases of the fallopian tubes are a major cause of infertility and tubal pregnancy. Until recently, diagnosis and treatment of tubal disease has been hampered by the difficulty of accessing and imaging the interior of the fallopian tubes in a least invasive manner. Such difficulties, however, have been largely overcome by the present availability of very small guidewires, catheters, and fiberoptic viewing scopes, usually referred to as falloposcopes. Particular systems and methods employing a hysteroscope in combination with the guidewire and small diameter fallopian access catheter for accessing and viewing the interior of the fallopian tubes are described in Kerin et al. (1990) *Fertil. Steril.* 54:390–400 and *J. Laparo. Endoscopic Surg.* 1:47–56, and copending patent application Ser. No. 08/207,475, assigned to the assignee of the present application.

A common medical procedure for imaging the uterus and fallopian tubes is referred to as hysterosalpingography. Such procedures rely on injecting contrast media into the uterus and fallopian tubes using a uterine access catheter having an elastomeric balloon near its distal end for sealing against the cervix. The anatomical structures of the uterus and fallopian tubes are then filled with contrast media fluoroscopically imaged in a conventional manner. In some cases, however, contrast media injected into the uterus does not fully pass into the fallopian tubes. If the fallopian tubes are not filled with the contrast media, subsequent imaging may be inadequate.

In such circumstances, it has been proposed to pass a pair of coaxial catheters through the uterine access catheter in order to access the fallopian tubes. In particular, an outer catheter is used to engage the fallopian os and a smaller tubular catheter is passed through the outer catheter and into the fallopian tube. Contrast media can then be injected directly into the fallopian tube for improved imaging. Such systems are described in U.S. Pat. No. 5,372,584.

While such coaxial catheter systems for selectively accessing the uterus and fallopian tubes are generally successful, they rely on using a relatively large diameter uterine access catheter. In particular, the uterine access catheter must be sufficiently large to pass the coaxial catheter system which is used to enter the fallopian tubes. The need to pass a larger catheter through the cervix significantly increases patient discomfort and can be more difficult for the physician to insert. While it would be possible to initially employ a small catheter for contrast media introduction, subsequent fallopian tube access would then require use of a second, larger uterine access catheter, thus increasing the cost and complexity of the procedure.

A further deficiency of presently utilized uterine access systems is the inability to or difficulty of manipulating the uterus during the hysterosalpingography or other imaging procedure. Frequently, it would be desirable to reorient the uterus to improve the fluoroscopic image or for other purposes. While a variety of uterine manipulating devices exist, most are incapable of fluid injection for fluoroscopic imaging. While combination uterine injectors and manipulators do exist, such as those available from BEI Medical Systems, Inc., under the tradenames ZUMI AND ZUI (which are generally described in U.S. Pat. No. 4,430,076), the handle which is attached over the balloon catheter for engaging the interior surface of the cervical os is difficult to properly position over the inner balloon catheter. Moreover, the handle is useful only for manipulation and does not provide uterine access for the introduction of other uterine and/or fallopian catheters. In contrast, the catheter system described in U.S. Pat. No. 5,372,584, is not useful for uterine manipulation. The '584 catheter has a disk which engages the outside of the cervix to maintain a seal. While sufficient to provide the desired seal, if the '584 catheter were used to manipulate the uterus, the seal provided by the disk would be stressed and the seal lost.

For these reasons, it would be desirable to provide improved apparatus and methods for accessing and manipulating the uterus in hysterosalpingography and other procedures. Such apparatus and methods will preferably provide for the introduction of a small diameter balloon catheter having a sleeve catheter thereover, where the assembly of the balloon catheter and sleeve catheter together provides sufficient rigidity and column strength to permit manipulation of the uterus and wherein the balloon catheter may be withdrawn from the sleeve catheter to permit use of the sleeve catheter for other purposes, such as the introduction of uterine and/or fallopian tube catheters. Such apparatus and methods should reduce the complexity and cost of performing hysterosalpingography and other related uterine and fallopian tube access procedures. It would further desirable if such apparatus were useful for other gynecological procedures, such as treatment of proximal tubal occlusion, endoscopic tubal examination, transcervical gamete intrafallopian transfer (GIFT), therapeutic drug delivery for treatment of infections and ectopic pregnancies, endometrial biopsy, intrauterine ultrasound, and the removal of myomas, polyps, and/or septums, and the like.

2. Description of the Background Art

U.S. Pat. No. 5,372,584, describes a catheter system for performing hysterosalpingography and selective salpingography. Catheter systems and methods for accessing the fallopian tubes are described in U.S. Pat. Nos. 5,389,089; 5,379,247; 5,300,023; and 5,147,315. Catheters intended for uterine access and/or manipulation are described in U.S. Pat. Nos. 5,259,836; 5,104,377, 4,496,345; 4,430,076; and WO 96/22122. Other catheter systems are described in U.S. Pat. Nos. 5,273,526 and 5,211,627. A cervical cannula is described in SU 730355. Laparoscopic cannulas comprising coaxial tubular members are described in U.S. Pat. Nos. 5,002,557 or 5,176,697. A cervical manipulator comprising an inner balloon member and other cervical cap is described in U.S. Pat. No. 5,209,754. Devices manufactured under U.S. Pat. No. 4,430,076, are sold by BEI Medical Systems under the trade name ZUMI, as described in a catalogue of BEI.

A coaxial catheter system for accessing and imaging a fallopian tube is described in copending application Ser. No. 08/207,475, filed on Mar. 7, 1994, assigned to the assignee of the present application, the full disclosure of which is incorporated herein by reference.

SUMMARY OF THE INVENTION

According to the present invention, apparatus and methods are provided for accessing, manipulating, and optionally

imaging a patient's uterus and fallopian tubes. The apparatus and methods are particularly suitable for use during the performance of hysterosalpingography where the uterus may be manipulated to improve the image obtained or for other purposes. The apparatus and methods further provide for accessing the fallopian tubes following the hysterosalpingography, but would also find use in a variety of other procedures requiring access to and manipulation of the uterus.

The apparatus and methods are particularly advantageous in that uterine access is provided by a small diameter, usually soft, catheter which is passed through the cervical os into the uterus. Uterine manipulation and subsequent catheter exchange are provided by a second, sleeve catheter which is disposed over the small diameter balloon catheter. The sleeve catheter has an atraumatic occluding member at its distal end which directly engages the interior surface of the cervical os. The occluding member is preferably formed as an inverted cone or "adorn" seal which partially penetrates and seals within the cervix in a manner that permits manipulation without the loss of seal. Together, the inner balloon catheter and sleeve catheter provide sufficient column strength and rigidity so that the uterus can be manipulated from the proximal end of the assembly of the two catheters. The individual catheters, however, are sufficiently small and soft so that the patient suffers minimum discomfort and trauma.

In a first aspect of the present invention, a uterine access catheter system comprises an inner catheter and a sleeve catheter. The inner catheter has a proximal end, a distal end, and a lumen therebetween. An inflatable balloon is positioned near the distal end of the inner catheter. The sleeve catheter has a proximal end, a distal end, and a lumen therebetween, and is sized to slidably receive the inner catheter therethrough. An occluding member is disposed near the distal end of the sleeve catheter and is configured to partially penetrate and seal against an anterior surface of the cervical os when the balloon of the inner catheter is positioned in the uterus. In particular, the sleeve catheter may be advanced distally over the inner catheter to provide for the desired engagement and seal. A locking mechanism is provided on the catheter assembly so that the sleeve catheter may be selectively fixed to the inner catheter to prevent relative axial movement therebetween. In this way, after the inner catheter is introduced and the balloon inflated, the sleeve catheter can be distally advanced to engage the distal occluding member against the anterior surface of the cervical os, providing a good seal and firm mechanical anchor. The sleeve catheter may then be locked to maintain such engagement and seal.

In a particular aspect of the access catheter system, both the inner catheter and the sleeve catheter have dimensions and physical characteristics selected to minimize patient trauma while maintaining sufficient mechanical strength to permit uterine manipulation. In particular, the inner catheter will have an outside diameter in the range from 1 mm to 2.5 mm, preferably from 1.5 mm to 2 mm, a lumen diameter in the range from 0.5 mm to 1.5 mm, usually in the range from 0.5 mm to 0.8 mm, and a length in the range from 25 cm to 40 cm. The sleeve catheter will preferably have an outside diameter in the range from 3 mm to 4.5 mm, usually from 3.3 mm to 4 mm, a lumen diameter in the range from 2 mm to 4 mm, usually from 2.5 mm to 3 mm, and a length in the range from 15 cm to 25 cm, usually from 15 cm to 20 cm. It is particularly preferred that the inner catheter be relatively soft, usually having a hardness in the range from 65D to 75D, preferably from 68D to 74D. The outer catheter will be somewhat harder, usually having a hardness in the range from 65D to 100D, preferably from 70D to 80D. By providing an inner catheter and sleeve catheter having hardnesses within these ranges, the desired mechanical strength is achieved without causing excessive patient discomfort or trauma.

In a specific aspect of the uterine access catheter system of the present invention, the occluding member on the sleeve catheter is formed as a conical plug having its apical end disposed in the distal direction. Optionally, the conical plug or other occluding member may be removably attached to the distal end of the sleeve catheter. Usually, the conical plug or other occluding member will be a resilient structure having a generally fixed geometry (i.e. not inflatable). In alternative embodiments of the present invention, however, the occluding member can be an inflatable balloon, usually having a similar conical configuration when inflated.

In yet another specific aspect of the uterine access catheter system of the present invention, the lock is configured to selectively fix a distal portion of the sleeve catheter to a distal portion of the inner catheter. By locking the inner catheter and sleeve catheter together near their respective distal ends, engagement of the cervix between the balloon and the occluding member may be enhanced. While the present invention contemplates that the catheter lock may be at any axial location within the catheter system, including near the proximal ends, locking mechanisms positioned at or near the proximal end will provide less locking rigidity between the distal ends of the catheters, and is therefore less preferred. Thus, it is preferred that the locking mechanism be dispersed to lock the inner matter to the sleeve catheter in a region within the distal-most 10 cm of the sleeve catheter, more preferably being within the distal-most 5 cm.

In the exemplary embodiment of the catheter lock, a feature is formed on an exterior surface of the inner catheter which selectively engages a mating feature on an inner surface of the sleeve catheter. For example, the feature on the exterior surface of the inner catheter may be a protrusion and the feature on the inner surface of the sleeve catheter may be a recess. After axially aligning the surface features, the catheters can be locked and unlocked to one another to be simply rotating the catheter to move the protrusion(s) and recess(es) in and out of engagement.

In a further specific aspect of the access catheter system in the present invention, the sleeve catheter may further comprise an exterior seal which seals over the interior surface of the cervix when the occluding is in the cervical os. Such a sealing member is particularly useful when the catheter system is provided with a vacuum connector which permits application of a vacuum between the occluding member and the balloon on the inner catheter when the cervix is being engaged therebetween. Application of such a vacuum acts to draw the occluding member into the cervical os, further enhancing engagement and sealing.

In other specific aspects of the uterine access catheter system of the present invention, the inner catheter may further include a hub at its proximal end, and the sleeve catheter may be introduced and removed over the distal end of the inner catheter. Usually, the distal balloon on the inner catheter is elastomeric and can be inflated to a width in the range from 10 mm to 15 mm. The system may further be provided with a stiffening rod that is removably received in the lumen of the inner catheter to facilitate introduction of the inner catheter through the cervical os at the initial stage of a procedure. The stiffening rod may be resilient or may be malleable. Malleable stiffening rods are less traumatic and

permit the physician to shape the stiffening rod according to the anatomy of a particular patient. Usually, the sleeve catheter will further include a handle or hub at its proximal end, and more usually the handle will comprise a connective fitting, such as a luer fitting.

In a second aspect of the present invention, methods for accessing the uterus comprise providing a catheter assembly generally as described above. The catheter assembly is introduced through the patient's vagina so that the balloon on the inner catheter is positioned past the cervix and lies within the uterus. The occluding member on the sleeve catheter is then engaged against an interior surface of the cervix, and the balloon inflated to seal against a posterior surface of the cervix. Usually, the balloon will be inflated first to facilitate advancing the occluding member against the cervix. After adequate engagement has been achieved, the sleeve catheter is locked to the inner catheter to prevent relative axial movement.

The catheter assembly introduced and anchored in place as described above is particularly useful for manually manipulating the position of the uterus during hysterosalpingography procedures or for other reasons. Such manual manipulation is achieved by moving the proximal end of the catheter assembly, where the manipulative forces are transmitted through the catheter assembly to the cervix and to within the uterus. The combined column strengths of the inner catheter and the sleeve catheter enhance such force transmission. The preferred dimensions and physical properties of the catheters are set forth above.

In a particularly preferred aspect of the method of the present invention, the locking step comprises rotating the inner catheter relative to the sleeve catheter to selectively engage a surface feature on the inner catheter with a surface feature on the outer catheter. By rotation, it is meant that at least one of the two catheters is rotated about its longitudinal axis relative to the other catheter. Of course, both catheters could be rotated in opposite directions until the desired engagement in locking is achieved. The catheters may then be disengaged by further rotating one catheter relative to the other. The preferred locking mechanisms utilized in the method are described above in connection with system.

Optionally, contrast media is introduced through the inner catheter into the uterus and imaging performed in a hysterosalpingography procedure. After such imaging, the catheters may be unlocked and the inner catheter withdrawn, leaving the sleeve catheter in place. A uterine catheter may then be introduced through the lumen of the sleeve catheter and guided to a fallopian tube falloposcope which can then be guided through the uterine catheter into the fallopian tube and the fallopian tube imaged. Alternatively, contrast media can be introduced through the fallopian tube catheter and the fallopian tube imaged by fluoroscopy. In yet another specific aspect of the method of the present invention, sealing between the occluding member on the sleeve catheter and the anterior surface of the cervical os may be enhanced by drawing a vacuum between the inflated balloon on the inner catheter and the occluding member. Optionally, the ability to draw the vacuum may be enhanced by positioning a seal over the exterior of the cervix before drawing the vacuum.

In still yet another specific aspect of the method of the present invention, the occluding member may be removed from the sleeve catheter after use, sterilized, and reused.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a uterine access catheter system constructed in accordance with the principles of the present invention.

FIG. **1A** is a detailed view with portions broken away of a portion of the sleeve catheter over the inner catheter of the catheter system of FIG. **1**, showing a preferred locking mechanism.

FIG. **1B** is a cross-sectional view taken along line 1B—1B of FIG. 1A.

FIG. **1C** is a cross-sectional view similar to that of FIG. 1B, except that the inner catheter and sleeve catheter have been rotated so that the locking mechanism is out of engagement.

FIG. **2** is an exploded view of the catheter system of FIG. 1.

FIG. **2A** is a detailed view of an alternative mounting mechanism for a removable occluding member of the sleeve catheter of the catheter system of FIG. **1**.

FIG. **2B** illustrates an alternative occluding member for the sleeve catheter of the catheter system of FIG. **1**, in the form of an inflatable balloon.

FIGS. **3A–3E** illustrate use of the catheter system of FIG. 1 for performing uterine manipulation and a hysterosalpingography procedure followed by accessing the fallopian tube with a fallopian catheter.

FIGS. **4–6** illustrate a modification to the sleeve catheter of the catheter system of FIG. **1** where an exterior cervical seal and vacuum connection are provided.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

A uterine access catheter system according to the present invention is illustrated in FIGS. **1**, **1A–1C**, and **2**. The catheter system **10** comprises two major components, the first of which is an inner catheter **12** having a proximal end **14**, a distal end **16**, and an inflatable balloon **18** near the distal end. A proximal hub **20** is secured to the proximal end **14** of the inner catheter **12** and includes an inflation port **22** and an axial lumen access port **24**. Typically a luer fitting **26** will be located at the proximal end of the proximal hub **20**.

The inner catheter **12** preferably comprises a flexible body formed from a soft material, usually a soft thermoplastic polymer or elastomer, such as a polyether block amide (pebax) having a hardness in the range set forth above. The inner catheter **12** will include an axial access lumen **28** and usually a separate inflation lumen (not shown) extending between inflation port **22** and the balloon **18**. The access lumen **28** will permit introduction of contrast media to the uterus, as will be described hereinafter. Additional lumens may also be provided, although there will usually be no additional lumens since it is desired to maintain a low profile for the inner catheter to facilitate entry through the cervical os. The preferred dimensions of the inner catheter **12** are set forth above.

The balloon **18** will usually be distensible, more usually being formed from an elastomeric material, optionally being formed from the same material as that used to form the catheter **12** itself. A useful balloon material is polyethylene. The balloon will have dimensions selected to permit inflation within the uterus on the posterior side of the cervical os, usually having a width in the range from 10 mm to 15 mm when fully inflated, more usually being generally spherical.

The second major component of the uterine access catheter system of the present invention is a sleeve catheter **30** which is usually in the form of a simple tube having only a single lumen therethrough and an occluding member **31** positioned at its distal end. Optionally, although not necessarily, a handle which may be in the form of a luer fitting **36** is secured to the proximal end **32** of the sleeve catheter **30**.

The occluding member **31** may be fixedly attached to the distal end of the sleeve catheter **30**, but will usually be removably attached thereto. For example, the occluding member **31** may be removably secured to the sleeve catheter **30** by a conventional threaded fitting, as illustrated in FIG. **2**, or may be secured to the sleeve catheter by spring-loaded balls **33** in the occluding member **31** and corresponding detents **35** on the distal end of the sleeve catheter **30**, as illustrated in FIG. **2**A. As yet another alternative, the occluding member **31** can be an inflatable balloon **31***a*, as illustrated in FIG. **2**B, where the inflated configuration is illustrated in broken line. It will be appreciated that the form of the occluding member is not critical so long as it can be selectively engaged against and sealed to the anterior side of the cervical os to permit both manipulation and fluid introduction according to the method of the present invention. Preferably, the geometry will be conical with the apical end disposed distally to partially penetrate and seal against the cervical os.

Referring now in particular to FIGS. **1**A–1C, the preferred locking mechanism for the coaxial catheters of the catheter system **10** of the present invention will be described. A plurality of protrusions **41** are formed on the outer surface of inner catheter **12**. The protrusions **41** may be in any form, but are preferably formed as small wedges or chevrons which engage similarly shaped recesses **43** formed in the inner surface of the sleeve catheter **30**. Preferably, a plurality of protrusions **41** will be axially aligned over one or more lines on the exterior surface of the inner catheter **12**. Most preferably, there will be two such lines on opposite sides of the outer surface of the inner catheter **12**. In this way, the inner catheter **12** and sleeve catheter **30** can be rotated relative to one another so that the protrusions **41** line up with the recesses **43**, as illustrated in FIG. **1**B, to lock the catheters together. The catheters can be unlocked simply by rotating the catheters further so that the protrusions **41** fall out of alignment with the recesses **43**, as illustrated in FIG. **1**C. Usually, more recesses will be provided on the interior surface of the sleeve catheter **30**, permitting locking over a range of axial positions. By orienting the wedge-shaped protrusions with the ramped surface declining in the distal direction, as illustrated in FIG. **1**A, particular strength is provided to draw proximally on the catheter assembly to manipulate the uterus. Disengagement can be then facilitated by advancing the inner catheter **12** relative to the sleeve.

A stiffening rod or mandrel **40** is optionally provided for inserting through the lumen **28** of the inner catheter **12**. The stiffening rod **40** improves the column strength of the inner catheter **12** to facilitate initial introduction through the cervix. After introduction, the stiffening rod **40** can be removed to clear the lumen for introduction of contrast media to perform hysterosalpingography or other procedures. The stiffening rod **40** may be composed of a malleable material, such as stainless steel.

The components of the uterine access catheter system **10** may be packaged separately, but will often be packaged together in a sterile package, such as a pouch, box, or other conventional packaging for medical devices. The uterine access catheter system may be used with other conventional and commercially available catheters for performing fallopian tube access, as described hereinbelow.

Use of the uterine access catheter system **10** of the present invention for performing hysterosalpingography and manipulating the uterus will now be described in connection with FIGS. **3**A–3D. Initially, the access catheter assembly **10** is introduced through the vaginal opening V so that balloon **18** is disposed past cervix C. The balloon is then inflated within the uterus U in order to block outflow from the uterus through the cervix C, as illustrated in FIG. **3**A. After appropriately positioning the inner catheter **12**, the sleeve catheter **30** is advanced distally over the inner catheter **12** until the occluding member **31** engages an anterior surface of the os of cervix C, as illustrated in FIG. **3**B. After the physician feels that the cervical os has been firmly captured between the balloon **18** and the occluding member **31**, the sleeve catheter **30** will be locked to the inner catheter **12** by rotating one relative to the other, as described above.

At this point, the catheter assembly is ready either for introduction of contrast media or other fluids through the inner catheter **12** or for manipulation of the uterus using the combined inner catheter **12** and outer sleeve catheter **30**. Fluid introduction is achieved through the fluid infusion port **24** on inner catheter **12**. Manipulation is achieved by the physician manually grasping a proximal portion of the catheter, typically near the handle **36** of sleeve catheter **30** and moving the assembly until the uterus is positioned in a desired manner.

After the initial hysterosalpingography or other procedures completed, the sleeve catheter **30** may be utilized for introduction of other fluid media or other catheters by first removing the inner catheter **12**. Such removal is accomplished by rotating the inner catheter relative to the sleeve catheter **30** until they are disengaged. Balloon **18** is deflated, and the inner catheter is withdrawn proximally through the lumen of sleeve catheter **30**, resulting in positioning of the sleeve catheter **30** as shown in FIG. **3**C. Fluids can be introduced by attaching to the luer fitting **36**. Alternatively, a uterine access catheter **50** may be positioned through the lumen of the sleeve catheter **30** into the uterus U, as shown in FIG. **3**D. Suitable uterine access catheters are available from commercial suppliers, such as Conceptus, Inc., San Carlos, Calif., under the trade name SOFTTORQUE™. The uterine catheter **50** is positioned so that a deflected end **52** lies adjacent the os of the fallopian tube FT. The uterine catheter **50** thus provides a secondary access lumen directly to the os.

After the uterine catheter **50** has been positioned, a fallopian catheter **60** is passed through the uterine catheter **50**, as illustrated in FIG. **3**E. Optionally, a guidewire (not illustrated) may be used to position the fallopian catheter **60** within the fallopian tube FT. The fallopian catheter **60** may then be used to provide improved imaging of the fallopian tube. For example, contrast media may be directly injected through the fallopian catheter **60** into the fallopian tube, and fluoroscopic imaging of the tube performed. Alternatively, a falloposcope (not shown) may be introduced through the fallopian catheter **60** and used to image the fallopian tube. Such catheters are commercially available from Conceptus, Inc. under the trade name VS™ catheter. Use of such falloposcopes for imaging a fallopian tube is described in copending application Ser. No. 08/207,475, the full disclosure of which has been previously incorporated herein by reference. The fallopian catheter may be used for other purposes, including treatment of proximal tubal occlusions, and transcervical gamete intrafallopian transfer (GIFT), therapeutic drug delivery for treatment of infectious and ectopic pregnancies, and endometrial biopsy, intrauterine ultrasound, removal of myomas, polyps, and/or septums and the like.

Referring now to FIGS. **4**–6, an alternative embodiment of the sleeve catheter of the catheter system of the present invention will be described. Sleeve catheter **50** comprises an inner tubular member **52** and an outer tubular member **54**.

The inner tubular member **52** and outer tubular member **54** are arranged coaxially and may be axially translated relative to each other. An occluding member **56** is mounted at the distal end of the inner tubular member **52**. A conical cup member **60** is disposed at the distal end of the outer tubular member **54**. A flexible seal **62** extends from the distal end of cup **60** to the proximal end of the occluding member **56**. By advancing the outer tubular member **54** distally relative to the inner tubular member **52**, the flexible seal **62** may be everted, as shown in FIG. **6**. In particular, the seal **62** may be everted so that it can engage and seal to the exterior of cervix C to enhance the sealing achieved on the anterior surface of the exterior os. Such sealing may be further enhanced by drawing a vacuum within the cervix C, conveniently by attaching a vacuum source to connector **70** which opens to the annular lumen between the inner luminal surface of inner tubular surface of inner tubular member **52** and the outer surface of inner catheter **12**, as shown in FIG. **6**. Typically, an "O-ring" or other appropriate seal will be provided distally of the vacuum connector **70** so that a vacuum can be drawn. Drawing a vacuum will further engage both the occluding member **56** and the seal **62** onto the cervix, assuring a fluid tight seal. Such application of a vacuum further enhances the mechanical engagement of the catheter system to the cervix, facilitating manipulation of the uterus as described previously.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

What is claimed is:

1. A method for performing hysterosalpingography on a patient, said method comprising:

providing a catheter assembly including (1) an inner catheter having a balloon near its distal end and (2) a sleeve catheter disposed coaxially over the inner catheter, wherein the sleeve catheter includes an atraumatic occluding member near its distal end;

introducing the catheter assembly through the patient's vagina so that the balloon is positioned past the cervix and in the uterus while the occluding member on the sleeve catheter engages outside the cervix;

inflating the balloon to seal against the cervix;

introducing contrast media through the inner catheter into the uterus;

imaging the uterus; and

advancing a distal end of the sleeve catheter over the inner catheter through the cervix and withdrawing the inner catheter from the sleeve catheter to leave an access lumen in the sleeve catheter through the cervix into the uterus.

2. A method as in claim **1**, further comprising:

introducing a uterine catheter through the lumen of the sleeve catheter and into the uterus after the sleeve catheter has been advanced into the uterus and the inner catheter removal from the sleeve catheter; and

guiding a distal end of the uterine catheter to the os at the entrance to a fallopian tube.

3. A method as in claim **2**, further comprising:

passing a fallopian catheter through a lumen of the uterine catheter and into the fallopian tube.

4. A method as in claim **3**, further comprising:

passing a falloposcope through a lumen of the fallopian catheter; and

imaging the fallopian tube using the falloposcope.

5. A method as in claim **3**, further comprising

introducing contrast media through the fallopian catheter into the fallopian tube; and

imaging the fallopian tube.

6. A method as in claim **1**, further comprising infusing of aspirating a fluid or material through the sleeve catheter into the uterus after the sleeve catheter has been advanced into the uterus and the inner catheter removed from the lumen of the sleeve catheter.

7. A method as in claim **1**, wherein the catheter system further comprises a stiffening rod that is removably received in a lumen of the inner catheter, wherein the stiffening rod is in place when the catheter system is introduced through the vagina and cervix and is removed prior to introducing contact media into the uterus.

8. A method as in claim **7**, wherein the stiffening rod is malleable and further comprising shaping a portion of the stiffening rod so that the inner catheter assumes a shape selected to match the patient's anatomy.

9. A uterine access catheter system comprising:

an inner catheter having a proximal end, a distal end, an access lumen therebetween, and an inflatable balloon near the distal end;

a sleeve catheter having a proximal end, a distal end, and a lumen therebetween sized to slidably receive the inner catheter, wherein the length of the sleeve catheter is less than the length of the inner catheter by at least 5 cm so that the distal end of the inner catheter can be introduced through a patient's cervix while the distal end of the sleeve catheter remains outside of the cervix; and

an occluding member on the distal end of the sleeve catheter adapted to engage against the outside of a cervical os when the inner catheter passes through the cervix and the sleeve catheter is placed over the inner catheter.

10. A uterine access catheter system as in claim **9**, wherein the inner catheter further includes a hub at its proximal end, wherein the sleeve catheter may be introduced and removed over the distal end of the inner catheter.

11. A uterine access catheter system as in claim **10**, wherein the inner catheter has an outside diameter in the range from 1 mm to 2.5 mm and a lumen diameter in the range from 0.5 mm to 1.5 mm, a length from 25 cm to 40 cm, and wherein the sleeve catheter has a lumen diameter in the range from 2 mm to 4 mm, an outside diameter in the range from 3 mm to 4.5 mm, and a length in the range from 15 cm to 25 cm.

12. A uterine access catheter system, as in claim **11**, wherein the distal balloon is elastomeric and can be inflated to a width in the range from 10 mm to 15 mm.

13. A uterine access catheter system, as in claim **9**, wherein the inner catheter is composed of a soft material having a hardness in the range from 65D to 75D, and the sleeve catheter is composed of a material having a hardness in the range from 70D to 80D.

14. A uterine access catheter system as in claim **9**, wherein the stiffening rod is malleable over at least a distal portion thereof.

15. A uterine access catheter system as in claim **9**, wherein the stiffening rod is resilient.

16. A uterine access catheter system as in claim **9**, wherein the sleeve catheter is more rigid than the inner catheter.

17. A uterine access catheter system as in claim **9**, wherein the sleeve catheter comprises a handle at its proximal end.

18. A uterine access catheter system as in claim 17, wherein the handle comprises a connectable fitting.

19. A method for performing hysterosalpingography on a patient, said method comprising:

providing a catheter assembly including (1) an inner catheter having a balloon near its distal end and (2) a sleeve catheter disposed coaxially over the inner catheter, wherein the sleeve catheter includes an atraumatic occluding member near its distal end;

introducing the catheter assembly through the patient's vagina so that the balloon is positioned past the cervix and in the uterus while the occluding member on the sleeve catheter engages outside the cervix;

inflating the balloon to seal against the cervix;

introducing contrast media through the inner catheter into the uterus;

imaging the uterus;

introducing a uterine catheter through the lumen of the sleeve catheter and into the uterus after the sleeve catheter has been advanced into the uterus and the inner catheter removal from the sleeve catheter; and

guiding a distal end of the uterine catheter to the os at the entrance to a fallopian tube

passing a falloposcope through a lumen of the fallopian catheter; and

imaging the fallopian tube using the falloposcope.

20. A method as in claim 19, further comprising

introducing contrast media through the fallopian catheter into the fallopian tube; and

imaging the fallopian tube.

21. A method as in claim 19, further comprising advancing the sleeve catheter into the uterus; removing the inner catheter from the lumen of the sleeve catheter; and infusing of aspirating a fluid or material through the sleeve catheter into the uterus.

22. A method as in claim 19, wherein the catheter system further comprises a stiffening rod that is removably received in a lumen of the inner catheter, wherein the stiffening rod is in place when the catheter system is introduced through the vagina and cervix and is removed prior to introducing contact media into the uterus.

23. A method as in claim 22, wherein the stiffening rod is malleable and further comprising shaping a portion of the stiffening rod so that the inner catheter assumes a shape selected to match the patient's anatomy.

24. A method for performing hysterosalpingography on a patient, said method comprising:

providing a catheter assembly including (1) an inner catheter having a balloon near its distal end, (2) a sleeve catheter disposed coaxially over the inner catheter, wherein the sleeve catheter includes an atraumatic occluding member near its distal end, and (3) a stiffening rod that is removably received in a lumen of the inner catheter;

introducing the catheter assembly through the patient's vagina with the stiffening rod in place in the inner catheter lumen so that the balloon is positioned past the cervix and in the uterus while the occluding member on the sleeve catheter engages outside the cervix;

inflating the balloon to seal against the cervix;

removing the stiffening rod; and

introducing contrast media through the inner catheter into the uterus;

imaging the uterus.

25. A method as in claim 24, further comprising:

introducing a uterine catheter through the lumen of the sleeve catheter and into the uterus after the sleeve catheter has been advanced into the uterus and the inner catheter removal from the sleeve catheter; and

guiding a distal end of the uterine catheter to the os at the entrance to a fallopian tube.

26. A method as in claim 24, further comprising:

passing a falloposcope through a lumen of the fallopian catheter; and

imaging the fallopian tube using the falloposcope.

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DOCUMENT-IDENTIFIER: US 5634883 A

TITLE: Apparatus for peritoneal retraction

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Abstract Text - ABTX (1):

A method and apparatus for mechanically lifting the abdominal wall away from underlying abdominal organs for laparoscopic surgery without insufflation. In the method an expansible device is inserted in the abdominal cavity through a small incision in a collapsed state and then expanded into engagement with an extensive area of the abdominal wall. Lifting force is then applied to the device for peritoneal retraction. The device takes the form of mechanical **rods** or arms and/or balloons. In the balloon embodiments lifting force may be applied externally of the abdominal cavity, or internally of the cavity by balloon inflation. Certain of the balloon embodiments are of an annular or U-shaped configuration and include a membrane for draping the internal organs and/or a centrally located balloon for lateral expansion. The balloons may be provided with an internal endoscope for viewing. The method also provides for laparoscopic gallbladder removal, either to the interior or exterior of the balloons. A needle is provided to laparoscopically pierce and drain the gallbladder. The needle carries a balloon **inflatable** to grip the gallbladder for retraction and removal.

Detailed Description Text - DETX (12):

The sixth embodiment is introduced into the abdominal cavity and used for retraction in generally the same manner depicted in FIG. 9 to 11, with the exception that after the arms 48.sub.a and 50.sub.a are fanned out, the balloons 54 and 56 would be inflated, as shown in FIG. 13. This expands and cushions the area of contact between the arms and abdominal wall. FIGS. 14 to 19 illustrate the preferred sequence for forming the incision 52 and introducing the fifth or sixth embodiment into the abdominal cavity. In FIG. 14, a Veress needle with a thin plastic sheath 60 forms a puncture in the abdominal wall and enters the abdominal cavity. The Veress needle is then withdrawn, leaving the sheath 60 in place as shown in FIG. 15 and the guidewire 62 is threaded through the sheath and into the abdominal cavity. A small incision 52 (0.5 cm) is then made along the sheath adjacent the guidewire and the sheath is removed, leaving the guidewire in place as shown in FIG. 16. A dilator 64 having a plastic guide sheath 66 thereover is then advanced over the guidewire and into the abdomen as shown in FIG. 17 and then the dilator and guidewire are removed, leaving the sheath in place as shown in FIG. 18. The dilator may have a fiberoptic scope to ensure that no bowel loops are impacted by the sheath during its placement. The lifting device or **retractor** is then introduced into the abdominal cavity through the guide sheath, as shown in FIG. 18, with the sheath protecting abdominal organs from trauma during insertion.

Thereafter, the arms 48 and 50 are fanned out to provide expanded engagement with the inside of the abdominal wall, as shown in FIG. 19. There it will also be seen that a mechanical arm 67 is being engaged with the levers 44 and 46 to impart lifting force thereto and, in turn, retract the abdominal wall. The arm 67 has a distal section 69.sub.a and a proximal section 69.sub.b connected by a lockable swivel 71. The proximal section is supported on a motorized worm gear actuator 73 mounted on the side of the operating table, designated 75.

Other Reference Publication - OREF (13):

M.M. Gazayerli, "The Gazayerli Endoscopic **Retractor** Model 1," Surgical Laparoscopy and Endoscopy, vol. 1, No. 2, 1991, pp. 98-100.